

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

CHANTIX (VARENICLINE)
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION
(NO. II)

This Document Relates to All Actions

22-MD-3050 (KPF)

22-MC-3050 (KPF)

Jury Trial Demanded

CONSOLIDATED MASTER CLASS ACTION COMPLAINT

The Consumer and Third-Party Payor (“TPP”) Plaintiffs (collectively “Plaintiffs”) file this Consolidated Class Action Complaint (“Master Class Complaint”) against Defendant Pfizer Inc. (“Pfizer”) relating to Pfizer’s manufacturing, distribution, and sale of adulterated, misbranded, and unapproved varenicline-containing drugs (“VCDs”).

INTRODUCTION

1. This case arises from Pfizer’s design, manufacture, marketing, distribution, packaging, and sale of VCDs under the brand name Chantix® that were contaminated with nitrosamine impurities and manufactured in a non-compliant manner with current Good Manufacturing Practices (“cGMPs”) in violation of various states’ laws. These VCDs were adulterated, non-merchantable, unfit for intended purpose, and not of the quality that Pfizer represented.

2. The brand name drug Chantix is known generically as varenicline and is a partial nicotine agonist. It is a first-line therapy in the treatment to help quit smoking. Unlike many other smoking-cessation aids, Chantix does not contain nicotine.

3. Pfizer obtained approval from the United States Food and Drug Administration (“FDA”) to sell Chantix as a first of its kind treatment in May 2006.

4. Chantix quickly became one of Pfizer's fastest growing products. Major media spending on Chantix totaled approximately \$55 million in 2007 (the year after its approval). In the year Chantix launched, Pfizer spent approximately \$4.3 million in medical journal advertisements alone.

5. The market rapidly embraced Chantix. For example, from its launch through 2015, the number of Chantix prescriptions for Medicaid beneficiaries increased 13,277%.¹

6. The price for Chantix steadily climbed since its launch. Price estimates at launch were approximately \$113.98, climbing to \$254.50 in 2015. By 2018, the price had more than doubled to \$485 for a 30-day supply, bringing in \$997 million in sales that year.²

7. Pfizer represented and warranted to consumers and TPPs that its VCDs were therapeutically equivalent to, and otherwise the same as, the actual FDA-approved brand name drug Chantix. Specifically, Pfizer represented and warranted that the VCDs were fit for their ordinary uses, merchantable, met the specifications of Defendant's FDA-approved labeling materials, and that it manufactured and distributed the VCDs in accordance with all applicable laws and regulations, including specifically cGMPs.

8. A therapeutic equivalent, among other things, must (i) have the same efficacy *and* safety as an approved drug, (ii) have the same identity, strength, quality, and purity as an approved drug, (iii) be adequately labeled, and (iv) be manufactured in compliance with cGMPs.³

¹ Xiaomeng Yue, et al., *Trends in Utilization, Spending, and Prices of Smoking-Cessation Medications in Medicaid Programs: 25 Years Empirical Data Analysis, 1991–2015*, AM. HEALTH DRUG BENEFITS, at 275-85 (Sept. 2018), www.ncbi.nlm.nih.gov/pmc/articles/PMC6207314/.

² Arlene Weintraub, *Price of Pfizer's smoking-cessation drug Chantix doubles in just 5 years: report*, FIERCE PHARMA (June 26, 2018), <https://www.fiercepharma.com/pfizer-hikes-price-smoking-cessation-drug-chantix-106-5-years-report>.

³ Orange Book Preface to 43rd Edition, U.S. FOOD & DRUG ADMIN. (Jan. 24, 2023), *available at* <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book->

9. In reality, however, Pfizer's VCDs were not therapeutically equivalent to FDA-approved Chantix. Its VCDs did not have the same safety profile, or same identity, strength, quality and purity, as FDA-approved Chantix because Pfizer's VCDs contained a dangerous, undisclosed nitrosamine known as N-nitroso-varenicline. Its VCDs also were not manufactured in a cGMP-compliant manner and therefore without any assurance the VCDs were of appropriate quality and were not properly labeled. When a drug is manufactured in a non-cGMP compliant manner, that means the manufacturer cannot assure that the drugs meet the appropriate quality, purity, identity or strength. Because a manufacturing process failure and testing/quality assurance failure lay at the heart of Pfizer's process for making VCDs, these products were not made in a cGMP-compliant manner, which rendered the products adulterated and misbranded, and therefore unsellable and worthless (or alternatively, certainly worth less), whether or not a given pill contained nitrosamines or not. *See, e.g.*, 21 U.S.C. § 351; *see also* 21 U.S.C. § 331.

10. As a result, Pfizer's VCDs were dangerous unapproved drugs, and were adulterated, misbranded, or both (and thereby rendered worthless, or alternatively, certainly worth less), through contamination with a genotoxic, probable human carcinogenic nitrosamine⁴ and lack of cGMP compliance concerning product testing, manufacture, and quality oversight. Indeed, Pfizer has a documented history of cGMP compliance failures at one, if not more, of its overseas facilities at which it manufactured and tested its VCDs.

[preface#:~:text=Any%20drug%20product%20in%20the,source%20or%20coded%20as%20non%2D.](#)

⁴ As discussed *infra*, the FDA, International Agency for Research on Cancer ("IARC"), European Medicines Agency ("EMA"), World Health Organization ("WHO"), U.S. Environmental Protection Agency ("EPA"), and other reputable agencies around the world consider nitrosamines to be genotoxic and probable human carcinogens.

11. Pfizer had actual or constructive notice of nitrosamine potential contamination and the dangerousness of these genotoxic, carcinogenic compounds. Nitrosamines and their routes of synthesis have been well known for decades. Scientific literature has long taught about nitrosamines, as well as their detection and avoidance. International scientific guidance endorsed by the FDA, EMA, and other regulatory bodies, identify nitrosamines as dangerous compounds within the “cohort of concern” that require manufacturers to characterize and control such impurities.⁵ And FDA guidance issued in 2019, in the wake of the 2018 valsartan recalls due to unprecedented nitrosamine contamination, made clear there was *no* acceptable levels of nitrosamines permitted any drugs at that time.⁶ All of the foregoing predated Pfizer’s VCD recalls beginning in the summer 2021 (see below).

12. Pfizer willfully disregarded the scientific and industry guidance, and knowingly and fraudulently manufactured, sold, labeled, marketed, or distributed adulterated or misbranded VCDs for purchase in the United States by consumers and TPPs.

13. In October 2020, Health Canada, the FDA analogue for Canada, asked all companies marketing a varenicline product (including Defendant Pfizer), to evaluate and test their products for nitrosamines.⁷

14. Pfizer’s own testing results provided to Health Canada showed undisclosed, impermissible N-nitroso-varenicline levels in Pfizer’s products. However, Pfizer apparently did

⁵ ICH Guidance for Industry, *M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*.

⁶ *General Advice Ltr.*, U.S. FOOD & DRUG ADMIN. (2019) (“FDA has determined that there is no acceptable specification for nitrosamines . . . Therefore, FDA advises that nitrosamines should be absent[.]”), available at <https://www.fda.gov/media/122643/download>.

⁷ *Champix (varenicline) – Potential Risk Posed by Long-Term Exposure to Nitrosamine Impurity, N-nitroso-varenicline, Exceeding Acceptable Intake Limits*, HEALTH CANADA (June 30, 2021), available at <https://recalls-rappels.canada.ca/en/alert-recall/champix-varenicline-potential-risk-posed-long-term-exposure-nitrosamine-impurity-n>.

not begin testing or recalling its VCDs in the United States until July 2021. At that time, the FDA confirmed Pfizer's VCD recalls were "because [the product] may contain levels of a nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit."⁸ Pfizer did not recall all of its VCDs at the time.

15. According to the FDA's testing in August 2021, Pfizer's VCDs contained staggeringly high levels of N-nitroso-varenicline in the range of 155-474 parts per million. These results were *more than fifty times higher* than the levels the FDA detected in another company's generic varenicline product.⁹

16. Finally, in September 2021—nearly one year after Health Canada directly asked Pfizer and other companies to evaluate and test their varenicline products for nitrosamines—Pfizer extended its recall to all VCDs sold in the United States.¹⁰ It has not reintroduced its VCDs into the market since.

17. In the wake of Pfizer's recalls, the FDA has granted emergency approval to two other companies' generic versions of Chantix. These products are made in such a way that nitrosamines are not present or controlled. This demonstrates there is an appropriate, cGMP-compliant way to make varenicline products, but Pfizer simply chose not to follow those procedures. Indeed, the levels of nitrosamines found in Pfizer's VCDs were so staggeringly high they would never pass the FDA new intake levels if Pfizer tried to sell its VCDs today.

⁸ *FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix>.

⁹ *Laboratory analysis of varenicline products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-varenicline-products>.

¹⁰ *Pfizer Expands Voluntary Nationwide Recall to include All Lots of CHANTIX® (Varenicline) Tablets Due to N-Nitroso Varenicline Content*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n>.

18. On information and belief, N-nitroso-varenicline contamination of Pfizer's VCDs dates back many years, at which point Pfizer had actual or, at a minimum, constructive notice of the contamination and cGMP failures concerning the testing, manufacture, and quality oversight of its VCDs. Indeed, because N-nitroso-varenicline contamination of VCDs is a process impurity (i.e., a byproduct of the chemical synthesis/manufacturing process), not a degradation or extraneous contaminant impurity, it would be expected that the nitrosamine would exist in every batch or lot.

19. Plaintiffs paid for and consumed (in the case of consumers), or paid for or reimbursed payment of (in the case of TPPs), contaminated VCDs that were illegally placed into the stream of commerce by Pfizer.

20. Plaintiffs paid for or made reimbursements for VCDs that were illegally and willfully introduced into the market by Pfizer, which caused them and thousands of other purchasers paying for or reimbursing prescriptions for these VCDs to sustain substantial economic damages as a result of paying for VCDs that were falsely represented as approved drugs, but that were not (and which were adulterated and/or misbranded) because of nitrosamine contamination and/or cGMP failures in the manufacture of the VCDs.

21. Additionally, Plaintiffs paid for or made reimbursements for VCDs that were illegally and willfully introduced into the market by Pfizer when they paid for VCDs that were adulterated and/or misbranded because they were not made in a cGMP-compliant manner (whether or not a particular tablet contained nitrosamines or not).

22. Pfizer's VCDs were not fit for their ordinary use and were not merchantable, and Pfizer has been unjustly enriched through the sale of these knowingly adulterated and misbranded drugs. Pfizer's conduct, as detailed in this Complaint, also constitutes actionable common law

fraud, consumer fraud, negligence and negligence per se, and negligent misrepresentation, and violates state laws and federal law (as incorporated by state laws).

23. Ironically, Pfizer's wrongful acts caused those people trying to use smoking products *less* to take a pill that contained an undisclosed, genotoxic carcinogen.

PARTIES

Consumer Plaintiffs

24. Plaintiff Juan Abreu is a citizen and/or resident of Florida. During the class period, Plaintiff Abreu paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Abreu that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Abreu bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Abreu known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Abreu would not have paid for Pfizer's VCDs. Indeed, Plaintiff Abreu would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Abreu's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant

Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Abreu would not have paid for the VCDs.

25. Plaintiff Mary Allen is a citizen and/or resident of New York. During the class period, Plaintiff Allen paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Allen that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Allen bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Allen known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Allen would not have paid for Pfizer's VCDs. Indeed, Plaintiff Allen would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Allen's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Allen would not have paid for the VCDs.

26. Plaintiff Theresa Baptiste is a citizen and/or resident of Pennsylvania. During the class period, Plaintiff Baptiste paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Baptiste that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Baptiste bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Baptiste known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Baptiste would not have paid for Pfizer's VCDs. Indeed, Plaintiff Baptiste would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Baptiste's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Baptiste would not have paid for the VCDs.

27. Plaintiff Timothy Bleeker is a citizen and/or resident of Washington. During the class period, Plaintiff Bleeker paid money for one or more of Pfizer's VCDs and purchased Pfizer's

VCDs. The product purchased bore a unique National Drug Code (“NDC”) which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Bleeker that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Bleeker bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Bleeker known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Bleeker would not have paid for Pfizer’s VCDs. Indeed, Plaintiff Bleeker would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Bleeker’s VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer’s deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Bleeker would not have paid for the VCDs.

28. Plaintiff Harold Bradley is a citizen and/or resident of Georgia. During the class period, Plaintiff Bradley paid money for one or more of Pfizer’s VCDs and purchased Pfizer’s VCDs. The product purchased bore a unique National Drug Code (“NDC”) which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer.

Pfizer expressly and impliedly warranted and represented to Plaintiff Bradley that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Bradley bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Bradley known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Bradley would not have paid for Pfizer's VCDs. Indeed, Plaintiff Bradley would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Bradley's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Bradley would not have paid for the VCDs.

29. Plaintiff Sharon Carroll is a citizen and/or resident of Washington. During the class period, Plaintiff Carroll paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Carroll that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for

ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Carroll bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Carroll known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Carroll would not have paid for Pfizer's VCDs. Indeed, Plaintiff Carroll would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Carroll's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Carroll would not have paid for the VCDs.

30. Plaintiff Karen Duff is a citizen and/or resident of Pennsylvania. During the class period, Plaintiff Duff paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Duff that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Duff bought a product that was contaminated with

a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Duff known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Duff would not have paid for Pfizer's VCDs. Indeed, Plaintiff Duff would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Duff's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Duff would not have paid for the VCDs.

31. Plaintiff Albert Edwards is a citizen and/or resident of Pennsylvania. During the class period, Plaintiff Edwards paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Edwards that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Edwards bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from

nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Edwards known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Edwards would not have paid for Pfizer's VCDs. Indeed, Plaintiff Edwards would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Edwards' VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Edwards would not have paid for the VCDs.

32. Plaintiff Tara Evans is a citizen and/or resident of Illinois. During the class period, Plaintiff Evans paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Evans that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Evans bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Evans known the product was not as represented because it was contaminated

with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Evans would not have paid for Pfizer's VCDs. Indeed, Plaintiff Evans would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Evans' VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Evans would not have paid for the VCDs.

33. Plaintiff Lillian Forrest is a citizen and/or resident of Pennsylvania. During the class period, Plaintiff Forrest paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Forrest that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Forrest bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Forrest known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Forrest would not have paid for Pfizer's VCDs. Indeed, Plaintiff Forrest would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination

and non-cGMP compliant manufacture of these VCDs, Plaintiff Forrest's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Forrest would not have paid for the VCDs.

34. Plaintiff Kimberly Hill is a citizen and/or resident of North Carolina. During the class period, Plaintiff Hill paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Hill that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Hill bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Hill known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Hill would not have paid for Pfizer's VCDs. Indeed, Plaintiff Hill would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Hill's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception

about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Hill would not have paid for the VCDs.

35. Plaintiff Valerie Hogue is a citizen and/or resident of Indiana and formerly of California. During the class period, while in California, Plaintiff Hogue paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Hogue that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Hogue bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Hogue known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Hogue would not have paid for Pfizer's VCDs. Indeed, Plaintiff Hogue would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Hogue's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Hogue would not have paid for the VCDs.

36. Plaintiff Douglas Houghton is a citizen and/or resident of Florida. During the class period, Plaintiff Houghton paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Houghton that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Houghton bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Houghton known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Houghton would not have paid for Pfizer's VCDs. Indeed, Plaintiff Houghton would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Houghton's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Houghton would not have paid for the VCDs.

37. Plaintiff James Jacobson is a citizen and/or resident of California. During the class period, Plaintiff Jacobson paid money for one or more of Pfizer's VCDs and purchased Pfizer's

VCDs. The product purchased bore a unique National Drug Code (“NDC”) which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Jacobson that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Jacobson bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Jacobson known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Jacobson would not have paid for Pfizer’s VCDs. Indeed, Plaintiff Jacobson would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Jacobson’s VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer’s deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Jacobson would not have paid for the VCDs.

38. Plaintiff Tammy LaMotte is a citizen and/or resident of Minnesota. During the class period, Plaintiff LaMotte paid money for one or more of Pfizer’s VCDs and purchased Pfizer’s VCDs. The product purchased bore a unique National Drug Code (“NDC”) which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by

Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff LaMotte that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff LaMotte bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff LaMotte known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff LaMotte would not have paid for Pfizer's VCDs. Indeed, Plaintiff LaMotte would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff LaMotte's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff LaMotte would not have paid for the VCDs.

39. Plaintiff Kathleen Lima is a citizen and/or resident of Minnesota. During the class period, Plaintiff Lima paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Lima that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary

and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Lima bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Lima known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Lima would not have paid for Pfizer's VCDs. Indeed, Plaintiff Lima would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Lima's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Lima would not have paid for the VCDs.

40. Plaintiff Clarence Massey is a citizen and/or resident of Michigan. During the class period, Plaintiff Massey paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Massey that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Massey bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake

limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Massey known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Massey would not have paid for Pfizer's VCDs. Indeed, Plaintiff Massey would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Massey's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Massey would not have paid for the VCDs.

41. Plaintiff Deborah Seeley is a citizen and/or resident of California. During the class period, Plaintiff Seeley paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Seeley that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Seeley bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination;

had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Seeley known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Seeley would not have paid for Pfizer's VCDs. Indeed, Plaintiff Seeley would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Seeley's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Seeley would not have paid for the VCDs.

42. Plaintiff Daniel Spence is a citizen and/or resident of Illinois. During the class period, Plaintiff Spence paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Spence that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Spence bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Spence known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner,

Plaintiff Spence would not have paid for Pfizer's VCDs. Indeed, Plaintiff Spence would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Spence's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Spence would not have paid for the VCDs.

43. Plaintiff Hazel Taylor is a citizen and/or resident of Michigan. During the class period, Plaintiff Taylor paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Taylor that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Taylor bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Taylor known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Taylor would not have paid for Pfizer's VCDs. Indeed, Plaintiff Taylor would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant

manufacture of these VCDs, Plaintiff Taylor's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Taylor would not have paid for the VCDs.

44. Plaintiff Carita Thompson is a citizen and/or resident of Illinois. During the class period, Plaintiff Thompson paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Thompson that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Thompson bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Thompson known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Thompson would not have paid for Pfizer's VCDs. Indeed, Plaintiff Thompson would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Thompson's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their

products and deficient manufacturing practices been made known earlier, Plaintiff Thompson would not have paid for the VCDs.

45. Plaintiff Daphne Walter is a citizen and/or resident of Oregon. During the class period, Plaintiff Walter paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Walter that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Walter bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Walter known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Walter would not have paid for Pfizer's VCDs. Indeed, Plaintiff Walter would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Walter's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Walter would not have paid for the VCDs.

46. Plaintiff Shannon Webb is a citizen and/or resident of New York. During the class period, Plaintiff Webb paid money for one or more of Pfizer's VCDs and purchased Pfizer's VCDs. The product purchased bore a unique National Drug Code ("NDC") which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Pfizer. Pfizer expressly and impliedly warranted and represented to Plaintiff Webb that the VCDs were FDA approved, the same as FDA-approved Chantix, were safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, and were made in a cGMP-compliant manner. But in fact, Plaintiff Webb bought a product that was contaminated with a nitrosamine of more than fifty times the eventual interim acceptable intake limit (per FDA testing). Further, the VCDs purchased also were not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Chantix; etc.). Had Plaintiff Webb known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Webb would not have paid for Pfizer's VCDs. Indeed, Plaintiff Webb would not have been able to purchase the VCDs in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of these VCDs, Plaintiff Webb's VCDs were adulterated, misbranded, and thus, worthless (or alternatively, certainly worth less) and illegally sold. Likewise, had Defendant Pfizer's deception about the impurities within their products and deficient manufacturing practices been made known earlier, Plaintiff Webb would not have paid for the VCDs.

TPP Plaintiffs

47. Plaintiff County of Monmouth is located in Freehold, New Jersey. County of Monmouth is a county and public entity organized and existing pursuant to Title 40 of the Laws

of the State of New Jersey and is a citizen of the State of New Jersey. County of Monmouth, by and through its appointed administrator, manages operations of sixty county departments comprised of more than 2,700 employees to deliver services to residents. County of Monmouth also operates a self-funded health insurance plan and workers' compensation plan for its employees and retirees and directly pays for all or a portion of its insureds' (including employees and dependents) healthcare costs, including but not limited to prescription costs.

48. County of Monmouth's Human Resources Benefits Division administers the County's self-funded employee benefit programs and employee enrollments. The programs include medical and prescription drug benefits to participants along with their dependents and retirees (collectively, "beneficiaries"). County of Monmouth's administers its health and welfare fund in New Jersey and its beneficiaries purchased VCDs in, inter alia, California, Connecticut, Delaware, Georgia, Indiana, Kentucky, Louisiana, Maine, Maryland, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Vermont, and Virginia. Beneficiaries of County of Monmouth purchased VCDs during the Class Period for personal use. County of Monmouth is ultimately at risk and responsible for reimbursing or paying for beneficiaries' purchases of prescription drugs. County of Monmouth paid more for VCDs than it would have absent Defendant's misconduct.

49. For example, and only to further demonstrate standing, County of Monmouth alleges some exemplar payments for the VCDs in the table below. In each instance, County of Monmouth received a request to reimburse a prescription drug on behalf of an enrollee for a particular date of service indicated below. County of Monmouth paid the amounts indicated for contaminated, non-cGMP compliant, FDA-recalled lots of VCDs. To be clear, the table below

does not demonstrate all of County of Monmouth's payments for VCDs, let alone all of the County of Monmouth's damages.

DATE	COST	NDC	LABEL NAME
2/24/2015	\$253.96	69046856	CHANTIX 0.5 MG TABLET
2/26/2015	\$248.96	69046956	CHANTIX 1 MG TABLET
2/26/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
2/27/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
3/1/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
3/11/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
3/19/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
3/19/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
3/23/2015	\$251.09	69046856	CHANTIX 0.5 MG TABLET
3/26/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
3/28/2015	\$268.96	69046856	CHANTIX 0.5 MG TABLET
3/30/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
3/30/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
4/2/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
4/2/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
4/3/2015	\$268.96	69046956	CHANTIX 1 MG TABLET
4/13/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
4/15/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
4/16/2015	\$268.96	69046956	CHANTIX 1 MG TABLET
4/20/2015	\$248.96	69046956	CHANTIX 1 MG TABLET
4/30/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
5/7/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
5/7/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
5/14/2015	\$268.96	69046956	CHANTIX 1 MG TABLET
5/15/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
5/21/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
5/26/2015	\$251.09	69046912	CHANTIX 1 MG CONT MONTH BOX
5/26/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
5/29/2015	\$251.09	69047102	CHANTIX STARTING MONTH BOX
5/29/2015	\$251.09	69046956	CHANTIX 1 MG TABLET
6/2/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
6/8/2015	\$271.22	69046956	CHANTIX 1 MG TABLET
6/10/2015	\$134.05	69046912	CHANTIX 1 MG CONT MONTH BOX
6/11/2015	\$286.22	69046956	CHANTIX 1 MG TABLET
6/15/2015	\$266.22	69046956	CHANTIX 1 MG TABLET
6/20/2015	\$286.22	69046956	CHANTIX 1 MG TABLET
6/25/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
6/30/2015	\$267.20	69047102	CHANTIX STARTING MONTH BOX
7/7/2015	\$267.20	69047102	CHANTIX STARTING MONTH BOX
7/7/2015	\$267.20	69047102	CHANTIX STARTING MONTH BOX

7/9/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
7/13/2015	\$286.22	69046956	CHANTIX 1 MG TABLET
7/19/2015	\$266.22	69046956	CHANTIX 1 MG TABLET
7/22/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
7/23/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
7/28/2015	\$286.22	69046956	CHANTIX 1 MG TABLET
7/30/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
8/1/2015	\$134.05	69046956	CHANTIX 1 MG TABLET
8/3/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
8/6/2015	\$267.20	69047102	CHANTIX STARTING MONTH BOX
8/17/2015	\$286.22	69046956	CHANTIX 1 MG TABLET
8/21/2015	\$777.47	69046956	CHANTIX 1 MG TABLET
8/25/2015	\$266.22	69046956	CHANTIX 1 MG TABLET
9/15/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
9/26/2015	\$266.22	69046956	CHANTIX 1 MG TABLET
9/28/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
9/29/2015	\$134.05	69046956	CHANTIX 1 MG TABLET
10/7/2015	\$286.22	69046956	CHANTIX 1 MG TABLET
10/22/2015	\$267.20	69046903	CHANTIX 1 MG CONT MONTH BOX
10/29/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
10/31/2015	\$266.22	69046956	CHANTIX 1 MG TABLET
11/10/2015	\$271.22	69046956	CHANTIX 1 MG TABLET
11/16/2015	\$267.20	69046903	CHANTIX 1 MG CONT MONTH BOX
11/18/2015	\$267.20	69047103	CHANTIX STARTING MONTH BOX
11/20/2015	\$267.20	69046903	CHANTIX 1 MG CONT MONTH BOX
11/28/2015	\$267.20	69046903	CHANTIX 1 MG CONT MONTH BOX
11/28/2015	\$267.20	69047103	CHANTIX STARTING MONTH BOX
12/1/2015	\$267.20	69047103	CHANTIX STARTING MONTH BOX
12/7/2015	\$271.22	69046956	CHANTIX 1 MG TABLET
12/8/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
12/16/2015	\$777.47	69046956	CHANTIX 1 MG TABLET
12/18/2015	\$267.20	69047102	CHANTIX STARTING MONTH BOX
12/18/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
12/19/2015	\$267.20	69047103	CHANTIX STARTING MONTH BOX
12/26/2015	\$267.20	69046912	CHANTIX 1 MG CONT MONTH BOX
1/4/2016	\$290.31	69047103	CHANTIX STARTING MONTH BOX
1/4/2016	\$529.41	69046903	CHANTIX 1 MG CONT MONTH BOX
1/5/2016	\$292.32	69046903	CHANTIX 1 MG CONT MONTH BOX
1/19/2016	\$292.32	69046903	CHANTIX 1 MG CONT MONTH BOX
2/8/2016	\$313.14	69046956	CHANTIX 1 MG TABLET
2/9/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
2/10/2016	\$292.32	69046903	CHANTIX 1 MG CONT MONTH BOX
2/10/2016	\$277.32	69046912	CHANTIX 1 MG CONT MONTH BOX
2/10/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
2/10/2016	\$292.32	69046903	CHANTIX 1 MG CONT MONTH BOX

2/15/2016	\$292.32	69046903	CHANTIX 1 MG CONT MONTH BOX
2/16/2016	\$529.41	69046903	CHANTIX 1 MG CONT MONTH BOX
2/23/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
3/3/2016	\$157.02	69046956	CHANTIX 1 MG TABLET
3/8/2016	\$277.32	69046903	CHANTIX 1 MG CONT MONTH BOX
3/9/2016	\$292.32	69046912	CHANTIX 1 MG CONT MONTH BOX
3/11/2016	\$835.83	69046956	CHANTIX 1 MG TABLET
3/23/2016	\$272.32	69046903	CHANTIX 1 MG CONT MONTH BOX
3/29/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
4/3/2016	\$292.32	69046903	CHANTIX 1 MG CONT MONTH BOX
4/5/2016	\$277.32	69046903	CHANTIX 1 MG CONT MONTH BOX
4/5/2016	\$313.14	69046956	CHANTIX 1 MG TABLET
4/13/2016	\$529.76	69046903	CHANTIX 1 MG CONT MONTH BOX
4/13/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
4/15/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
4/21/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
4/22/2016	\$292.32	69046856	CHANTIX 0.5 MG TABLET
4/27/2016	\$313.14	69046956	CHANTIX 1 MG TABLET
4/28/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
4/30/2016	\$292.32	69046912	CHANTIX 1 MG CONT MONTH BOX
4/30/2016	\$292.32	69047103	CHANTIX STARTING MONTH BOX
5/4/2016	\$316.92	69046903	CHANTIX 1 MG CONT MONTH BOX
5/5/2016	\$295.85	69046903	CHANTIX 1 MG CONT MONTH BOX
5/7/2016	\$58.84	69046856	CHANTIX 0.5 MG TABLET
5/7/2016	\$316.92	69046956	CHANTIX 1 MG TABLET
5/9/2016	\$295.85	69047103	CHANTIX STARTING MONTH BOX
5/12/2016	\$295.85	69046903	CHANTIX 1 MG CONT MONTH BOX
5/12/2016	\$295.85	69047103	CHANTIX STARTING MONTH BOX
5/15/2016	\$295.85	69047103	CHANTIX STARTING MONTH BOX
5/23/2016	\$295.85	69047103	CHANTIX STARTING MONTH BOX
5/23/2016	\$873.87	69046956	CHANTIX 1 MG TABLET
5/25/2016	\$306.39	69046903	CHANTIX 1 MG CONT MONTH BOX
5/31/2016	\$316.92	69046903	CHANTIX 1 MG CONT MONTH BOX
6/9/2016	\$339.05	69046956	CHANTIX 1 MG TABLET
6/12/2016	\$339.05	69046956	CHANTIX 1 MG TABLET
6/20/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
6/20/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
6/21/2016	\$327.78	69046903	CHANTIX 1 MG CONT MONTH BOX
6/26/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
6/30/2016	\$339.05	69046956	CHANTIX 1 MG TABLET
7/5/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
7/6/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
7/12/2016	\$301.50	69046903	CHANTIX 1 MG CONT MONTH BOX
7/25/2016	\$295.85	69046912	CHANTIX 1 MG CONT MONTH BOX
7/25/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX

8/3/2016	\$339.05	69046956	CHANTIX 1 MG TABLET
8/9/2016	\$316.50	69046956	CHANTIX 1 MG TABLET
8/10/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
8/15/2016	\$301.50	69046903	CHANTIX 1 MG CONT MONTH BOX
8/18/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
8/18/2016	\$920.03	69046956	CHANTIX 1 MG TABLET
8/20/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
9/8/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
9/9/2016	\$339.05	69046956	CHANTIX 1 MG TABLET
9/9/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
9/12/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
9/15/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
9/22/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
9/26/2016	\$316.50	69046956	CHANTIX 1 MG TABLET
9/28/2016	\$296.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/3/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/4/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
10/10/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/11/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/12/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
10/12/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/13/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/13/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/17/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
10/27/2016	\$316.50	69046956	CHANTIX 1 MG TABLET
10/31/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
11/6/2016	\$301.50	69046903	CHANTIX 1 MG CONT MONTH BOX
11/9/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
11/15/2016	\$311.03	69046903	CHANTIX 1 MG CONT MONTH BOX
11/16/2016	\$316.50	69046956	CHANTIX 1 MG TABLET
11/16/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
11/16/2016	\$944.31	69046956	CHANTIX 1 MG TABLET
11/18/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
11/29/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
12/2/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
12/6/2016	\$324.05	69046956	CHANTIX 1 MG TABLET
12/8/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
12/8/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
12/11/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
12/13/2016	\$339.05	69046956	CHANTIX 1 MG TABLET
12/14/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
12/16/2016	\$316.51	69047103	CHANTIX STARTING MONTH BOX
12/16/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
12/30/2016	\$316.50	69046903	CHANTIX 1 MG CONT MONTH BOX
1/2/2017	\$346.29	69047103	CHANTIX STARTING MONTH BOX

1/6/2017	\$346.29	69046903	CHANTIX 1 MG CONT MONTH BOX
1/11/2017	\$370.96	69046956	CHANTIX 1 MG TABLET
1/11/2017	\$346.29	69046903	CHANTIX 1 MG CONT MONTH BOX
1/12/2017	\$346.29	69047103	CHANTIX STARTING MONTH BOX
1/14/2017	\$341.69	69046903	CHANTIX 1 MG CONT MONTH BOX
1/23/2017	\$346.29	69046903	CHANTIX 1 MG CONT MONTH BOX
1/24/2017	\$355.96	69046956	CHANTIX 1 MG TABLET
1/30/2017	\$341.79	69046903	CHANTIX 1 MG CONT MONTH BOX
2/1/2017	\$346.29	69046903	CHANTIX 1 MG CONT MONTH BOX
2/3/2017	\$346.29	69046903	CHANTIX 1 MG CONT MONTH BOX
2/5/2017	\$346.29	69046903	CHANTIX 1 MG CONT MONTH BOX
2/6/2017	\$346.29	69047103	CHANTIX STARTING MONTH BOX
2/14/2017	\$355.96	69046956	CHANTIX 1 MG TABLET
2/16/2017	\$356.79	69047103	CHANTIX STARTING MONTH BOX
2/18/2017	\$370.96	69046956	CHANTIX 1 MG TABLET
2/22/2017	\$346.29	69047103	CHANTIX STARTING MONTH BOX
3/2/2017	\$981.46	69046956	CHANTIX 1 MG TABLET
3/13/2017	\$341.81	69047103	CHANTIX STARTING MONTH BOX
3/13/2017	\$341.81	69046903	CHANTIX 1 MG CONT MONTH BOX
3/13/2017	\$326.91	69046903	CHANTIX 1 MG CONT MONTH BOX
3/24/2017	\$346.17	69046956	CHANTIX 1 MG TABLET
4/5/2017	\$341.81	69047103	CHANTIX STARTING MONTH BOX
4/7/2017	\$346.29	69047103	CHANTIX STARTING MONTH BOX
4/19/2017	\$341.81	69046903	CHANTIX 1 MG CONT MONTH BOX
4/19/2017	\$341.81	69047103	CHANTIX STARTING MONTH BOX
5/2/2017	\$341.81	69047103	CHANTIX STARTING MONTH BOX
5/5/2017	\$341.81	69046903	CHANTIX 1 MG CONT MONTH BOX
5/16/2017	\$326.91	69046903	CHANTIX 1 MG CONT MONTH BOX
5/26/2017	\$346.29	69046903	CHANTIX 1 MG CONT MONTH BOX
5/30/2017	\$326.91	69046903	CHANTIX 1 MG CONT MONTH BOX
6/2/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
6/8/2017	\$1,045.64	69046956	CHANTIX 1 MG TABLET
7/10/2017	\$369.70	69046956	CHANTIX 1 MG TABLET
7/12/2017	\$389.70	69046856	CHANTIX 0.5 MG TABLET
7/17/2017	\$1,060.64	69046956	CHANTIX 1 MG TABLET
7/20/2017	\$348.87	69046903	CHANTIX 1 MG CONT MONTH BOX
8/3/2017	\$348.87	69046903	CHANTIX 1 MG CONT MONTH BOX
8/7/2017	\$368.54	69047103	CHANTIX STARTING MONTH BOX
8/27/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
8/27/2017	\$363.77	69046903	CHANTIX 1 MG CONT MONTH BOX
8/29/2017	\$348.87	69046903	CHANTIX 1 MG CONT MONTH BOX
9/8/2017	\$195.25	69046856	CHANTIX 0.5 MG TABLET
9/27/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
9/28/2017	\$1,060.64	69046956	CHANTIX 1 MG TABLET
10/11/2017	\$389.70	69046956	CHANTIX 1 MG TABLET

10/16/2017	\$292.01	69046912	CHANTIX 1 MG CONT MONTH BOX
10/25/2017	\$363.77	69046903	CHANTIX 1 MG CONT MONTH BOX
11/1/2017	\$363.77	69046903	CHANTIX 1 MG CONT MONTH BOX
11/3/2017	\$389.70	69046856	CHANTIX 0.5 MG TABLET
11/7/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
11/9/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
11/9/2017	\$363.77	69046903	CHANTIX 1 MG CONT MONTH BOX
11/16/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
11/16/2017	\$363.77	69046956	CHANTIX 1 MG TABLET
11/20/2017	\$369.70	69046956	CHANTIX 1 MG TABLET
11/26/2017	\$348.87	69046903	CHANTIX 1 MG CONT MONTH BOX
11/28/2017	\$1,045.64	69046956	CHANTIX 1 MG TABLET
12/2/2017	\$974.93	69046903	CHANTIX 1 MG CONT MONTH BOX
12/3/2017	\$363.77	69046903	CHANTIX 1 MG CONT MONTH BOX
12/12/2017	\$363.77	69046903	CHANTIX 1 MG CONT MONTH BOX
12/22/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
12/23/2017	\$363.77	69046903	CHANTIX 1 MG CONT MONTH BOX
12/27/2017	\$343.77	69046956	CHANTIX 1 MG TABLET
12/28/2017	\$363.77	69047103	CHANTIX STARTING MONTH BOX
1/2/2018	\$1,153.50	69046956	CHANTIX 1 MG TABLET
1/8/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
1/9/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
1/11/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
1/12/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
1/20/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
1/25/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
1/25/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
1/27/2018	\$291.91	69046912	CHANTIX 1 MG CONT MONTH BOX
2/6/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
2/8/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
2/13/2018	\$397.94	69046856	CHANTIX 0.5 MG TABLET
2/14/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
2/14/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
2/26/2018	\$1,153.60	69046956	CHANTIX 1 MG TABLET
2/27/2018	\$1,075.70	69046903	CHANTIX 1 MG CONT MONTH BOX
3/7/2018	\$397.94	69046956	CHANTIX 1 MG TABLET
3/8/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
3/9/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
3/12/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
3/18/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
4/4/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
4/4/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
4/4/2018	\$397.94	69046956	CHANTIX 1 MG TABLET
4/6/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
4/12/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX

4/18/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
4/27/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
5/4/2018	\$398.04	69047103	CHANTIX STARTING MONTH BOX
5/23/2018	\$398.04	69046903	CHANTIX 1 MG CONT MONTH BOX
5/27/2018	\$397.94	69046956	CHANTIX 1 MG TABLET
5/31/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
6/13/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
6/27/2018	\$1,090.70	69046903	CHANTIX 1 MG CONT MONTH BOX
7/11/2018	\$425.75	69046956	CHANTIX 1 MG TABLET
7/12/2018	\$425.85	69047103	CHANTIX STARTING MONTH BOX
7/16/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
7/16/2018	\$426.31	69046856	CHANTIX 0.5 MG TABLET
7/23/2018	\$213.51	69046956	CHANTIX 1 MG TABLET
7/30/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
8/11/2018	\$426.31	69046856	CHANTIX 0.5 MG TABLET
8/12/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
8/14/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
8/23/2018	\$397.94	69046956	CHANTIX 1 MG TABLET
8/27/2018	\$1,153.60	69046956	CHANTIX 1 MG TABLET
8/28/2018	\$397.94	69046903	CHANTIX 1 MG CONT MONTH BOX
8/29/2018	\$426.41	69046956	CHANTIX 1 MG TABLET
8/30/2018	\$397.94	69047103	CHANTIX STARTING MONTH BOX
9/2/2018	\$363.63	69046903	CHANTIX 1 MG CONT MONTH BOX
9/6/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
9/9/2018	\$431.62	69046856	CHANTIX 0.5 MG TABLET
9/19/2018	\$1,075.70	69046903	CHANTIX 1 MG CONT MONTH BOX
9/22/2018	\$402.90	69046903	CHANTIX 1 MG CONT MONTH BOX
9/25/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
9/26/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
9/26/2018	\$402.90	69046903	CHANTIX 1 MG CONT MONTH BOX
10/2/2018	\$382.90	69046903	CHANTIX 1 MG CONT MONTH BOX
10/2/2018	\$1,075.70	69046903	CHANTIX 1 MG CONT MONTH BOX
10/5/2018	\$402.90	69046956	CHANTIX 1 MG TABLET
10/8/2018	\$431.62	69046856	CHANTIX 0.5 MG TABLET
10/24/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
10/28/2018	\$402.90	69046903	CHANTIX 1 MG CONT MONTH BOX
11/2/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
11/7/2018	\$431.62	69046856	CHANTIX 0.5 MG TABLET
11/12/2018	\$402.90	69046903	CHANTIX 1 MG CONT MONTH BOX
11/13/2018	\$216.24	69046956	CHANTIX 1 MG TABLET
11/14/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
11/17/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
11/17/2018	\$402.90	69046903	CHANTIX 1 MG CONT MONTH BOX
12/3/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
12/4/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX

12/15/2018	\$431.62	69046856	CHANTIX 0.5 MG TABLET
12/19/2018	\$1,075.70	69046903	CHANTIX 1 MG CONT MONTH BOX
12/27/2018	\$402.90	69047103	CHANTIX STARTING MONTH BOX
12/27/2018	\$1,168.60	69046956	CHANTIX 1 MG TABLET
12/28/2018	\$560.21	69046956	CHANTIX 1 MG TABLET
1/3/2019	\$402.90	69046956	CHANTIX 1 MG TABLET
1/4/2019	\$402.90	69046956	CHANTIX 1 MG TABLET
1/7/2019	\$402.90	69047103	CHANTIX STARTING MONTH BOX
1/7/2019	\$402.90	69047103	CHANTIX STARTING MONTH BOX
1/9/2019	\$402.90	69047103	CHANTIX STARTING MONTH BOX
1/9/2019	\$402.90	69047103	CHANTIX STARTING MONTH BOX
1/9/2019	\$402.90	69046903	CHANTIX 1 MG CONT MONTH BOX
1/9/2019	\$402.90	69046903	CHANTIX 1 MG CONT MONTH BOX
1/14/2019	\$411.62	69046856	CHANTIX 0.5 MG TABLET
1/15/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
1/21/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
1/29/2019	\$423.00	69046856	CHANTIX 0.5 MG TABLET
2/5/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
2/6/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
2/6/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
2/14/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
2/18/2019	\$589.23	69046956	CHANTIX 1 MG TABLET
2/19/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
2/19/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
2/19/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
2/24/2019	\$423.00	69046856	CHANTIX 0.5 MG TABLET
2/25/2019	\$433.15	69046856	CHANTIX 0.5 MG TABLET
3/1/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
3/2/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
3/7/2019	\$423.00	69046856	CHANTIX 0.5 MG TABLET
3/8/2019	\$367.12	69046903	CHANTIX 1 MG CONT MONTH BOX
3/14/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
3/18/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
3/21/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
3/23/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
3/23/2019	\$423.00	69046856	CHANTIX 0.5 MG TABLET
3/28/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
4/5/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
4/5/2019	\$423.00	69046856	CHANTIX 0.5 MG TABLET
4/8/2019	\$1,227.32	69046956	CHANTIX 1 MG TABLET
4/12/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
4/15/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
4/16/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
4/20/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
4/20/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET

5/2/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
5/7/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
5/8/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
5/10/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
5/10/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
5/13/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
5/13/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
5/13/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
5/15/2019	\$1,145.53	69046903	CHANTIX 1 MG CONT MONTH BOX
5/20/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
5/25/2019	\$367.12	69046903	CHANTIX 1 MG CONT MONTH BOX
5/29/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
5/31/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
5/31/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
6/6/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
6/6/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
6/10/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
6/10/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
6/13/2019	\$423.31	69047103	CHANTIX STARTING MONTH BOX
6/13/2019	\$453.46	69046956	CHANTIX 1 MG TABLET
6/14/2019	\$1,212.32	69046956	CHANTIX 1 MG TABLET
6/28/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
7/3/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
7/7/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
7/10/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
7/10/2019	\$403.00	69046956	CHANTIX 1 MG TABLET
7/14/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
7/18/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
7/22/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
7/25/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
7/29/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
8/5/2019	\$453.15	69046856	CHANTIX 0.5 MG TABLET
8/12/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
8/15/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
8/21/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
8/22/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
8/28/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
8/30/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
9/3/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
9/3/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
9/6/2019	\$1,130.53	69046903	CHANTIX 1 MG CONT MONTH BOX
9/9/2019	\$227.00	69046956	CHANTIX 1 MG TABLET
9/27/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
9/27/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
10/2/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX

10/3/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
10/3/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
10/7/2019	\$1,212.32	69046956	CHANTIX 1 MG TABLET
10/8/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
10/9/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
10/14/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
10/16/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
10/16/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
10/18/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
10/18/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
10/21/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
10/22/2019	\$453.46	69046956	CHANTIX 1 MG TABLET
10/23/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
10/24/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
10/27/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
10/28/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
11/4/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
11/7/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
11/7/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
11/13/2019	\$1,130.53	69046903	CHANTIX 1 MG CONT MONTH BOX
11/13/2019	\$408.00	69046903	CHANTIX 1 MG CONT MONTH BOX
11/19/2019	\$423.00	69046956	CHANTIX 1 MG TABLET
12/2/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
12/4/2019	\$1,145.53	69046903	CHANTIX 1 MG CONT MONTH BOX
12/6/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
12/10/2019	\$423.00	69047103	CHANTIX STARTING MONTH BOX
12/10/2019	\$423.00	69046903	CHANTIX 1 MG CONT MONTH BOX
12/10/2019	\$408.00	69046956	CHANTIX 1 MG TABLET
12/11/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
12/21/2019	\$453.15	69046956	CHANTIX 1 MG TABLET
1/3/2020	\$444.12	69047103	CHANTIX STARTING MONTH BOX
1/4/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
1/6/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
1/6/2020	\$1,273.69	69046956	CHANTIX 1 MG TABLET
1/13/2020	\$429.12	69046903	CHANTIX 1 MG CONT MONTH BOX
2/2/2020	\$1,187.89	69046903	CHANTIX 1 MG CONT MONTH BOX
2/3/2020	\$475.78	69046956	CHANTIX 1 MG TABLET
2/3/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
2/6/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
2/26/2020	\$475.78	69046956	CHANTIX 1 MG TABLET
2/26/2020	\$475.78	69046956	CHANTIX 1 MG TABLET
3/4/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
3/4/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
3/16/2020	\$444.51	69047103	CHANTIX STARTING MONTH BOX
3/21/2020	\$475.78	69046956	CHANTIX 1 MG TABLET

3/27/2020	\$1,273.77	69046956	CHANTIX 1 MG TABLET
3/30/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
4/10/2020	\$475.78	69046956	CHANTIX 1 MG TABLET
4/18/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
4/22/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
4/24/2020	\$475.78	69046956	CHANTIX 1 MG TABLET
4/30/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
5/12/2020	\$475.78	69046956	CHANTIX 1 MG TABLET
5/18/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
5/18/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
5/23/2020	\$475.78	69046956	CHANTIX 1 MG TABLET
6/12/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
6/30/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
7/6/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
7/10/2020	\$444.12	69047103	CHANTIX STARTING MONTH BOX
7/24/2020	\$444.12	69047103	CHANTIX STARTING MONTH BOX
7/31/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
8/3/2020	\$1,273.77	69046956	CHANTIX 1 MG TABLET
8/11/2020	\$444.12	69046956	CHANTIX 1 MG TABLET
8/20/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
9/18/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
10/13/2020	\$475.78	69046856	CHANTIX 0.5 MG TABLET
10/20/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
10/25/2020	\$424.12	69046956	CHANTIX 1 MG TABLET
11/17/2020	\$424.12	69046903	CHANTIX 1 MG CONT MONTH BOX
11/23/2020	\$444.12	69047103	CHANTIX STARTING MONTH BOX
11/30/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
12/9/2020	\$1,273.77	69046956	CHANTIX 1 MG TABLET
12/22/2020	\$444.51	69047103	CHANTIX STARTING MONTH BOX
12/29/2020	\$444.12	69046903	CHANTIX 1 MG CONT MONTH BOX
12/30/2020	\$444.12	69047103	CHANTIX STARTING MONTH BOX
12/31/2020	\$444.51	69046903	CHANTIX 1 MG CONT MONTH BOX
1/13/2021	\$88.28	69046856	CHANTIX 0.5 MG TABLET
1/13/2021	\$334.97	69046956	CHANTIX 1 MG TABLET
1/26/2021	\$446.38	69046903	CHANTIX 1 MG CONT MONTH BOX
2/3/2021	\$446.38	69046903	CHANTIX 1 MG CONT MONTH BOX
2/3/2021	\$446.38	69047103	CHANTIX STARTING MONTH BOX
2/10/2021	\$446.38	69046903	CHANTIX 1 MG CONT MONTH BOX
2/12/2021	\$446.38	69047103	CHANTIX STARTING MONTH BOX
2/26/2021	\$446.38	69047103	CHANTIX STARTING MONTH BOX
3/3/2021	\$446.38	69047103	CHANTIX STARTING MONTH BOX
3/9/2021	\$446.38	69046956	CHANTIX 1 MG TABLET
3/11/2021	\$446.38	69046903	CHANTIX 1 MG CONT MONTH BOX
3/12/2021	\$1,294.73	69046956	CHANTIX 1 MG TABLET
3/26/2021	\$446.38	69047103	CHANTIX STARTING MONTH BOX

3/29/2021	\$1,222.44	69046903	CHANTIX 1 MG CONT MONTH BOX
4/15/2021	\$446.38	69046903	CHANTIX 1 MG CONT MONTH BOX
4/19/2021	\$446.38	69046956	CHANTIX 1 MG TABLET
4/19/2021	\$446.38	69046956	CHANTIX 1 MG TABLET
4/29/2021	\$478.21	69046856	CHANTIX 0.5 MG TABLET
4/30/2021	\$446.38	69047103	CHANTIX STARTING MONTH BOX
6/11/2021	\$446.38	69046903	CHANTIX 1 MG CONT MONTH BOX
6/14/2021	\$446.38	69046956	CHANTIX 1 MG TABLET
6/15/2021	\$478.21	69046856	CHANTIX 0.5 MG TABLET
6/16/2021	\$446.38	69046856	CHANTIX 0.5 MG TABLET
6/18/2021	\$446.77	69047103	CHANTIX STARTING MONTH BOX
7/1/2021	\$80.33	69046956	CHANTIX 1 MG TABLET
7/11/2021	\$398.63	69046956	CHANTIX 1 MG TABLET
7/16/2021	\$446.38	69046956	CHANTIX 1 MG TABLET
8/9/2021	\$446.73	60505476606	APO-VARENICLINE 1 MG TABLET
8/10/2021	\$424.09	60505476606	APO-VARENICLINE 1 MG TABLET
9/6/2021	\$416.95	60505476606	APO-VARENICLINE 1 MG TABLET
9/8/2021	\$424.09	60505476606	APO-VARENICLINE 1 MG TABLET
10/27/2021	\$227.54	60505476505	APO-VARENICLINE 0.5 MG TABLET
11/6/2021	\$401.79	49884015676	VARENICLINE 1 MG TABLET
11/22/2021	\$424.09	60505476606	APO-VARENICLINE 1 MG TABLET
12/9/2021	\$401.79	49884015676	VARENICLINE 1 MG TABLET
12/17/2021	\$424.09	60505476606	APO-VARENICLINE 1 MG TABLET
1/13/2022	\$424.09	60505476606	APO-VARENICLINE 1 MG TABLET
2/8/2022	\$363.99	49884015676	VARENICLINE 1 MG TABLET
2/13/2022	\$454.33	60505476606	APO-VARENICLINE 1 MG TABLET
2/14/2022	\$430.43	49884015676	VARENICLINE 1 MG TABLET

50. MSP Recovery Claims Series 44, LLC (“Series 44”), is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Series 44’s Amended and Restated Limited Liability Company Operating Agreement dated October 23, 2020, permits Series 44 to establish one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Series 44 established various designated series to serve as units of the company to maintain various claims recovery assignments separate from other company assets, and to account for and associate certain assets with certain particular series.

51. Series 44 has enumerated rights relating to its designated series under its Amended and Restated Limited Liability Company Operating Agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c).

52. Specifically, all rights and benefits arising from assignments to its series (including the assignments discussed below) belong to Series 44. Series 44 is authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series under its Amended and Restated Limited Liability Company Operating Agreement. Series 44 retained the legal right to sue on behalf of each designated series and pursue all rights, benefits, or causes of action arising from assignments to a series in its own name or in the name of the designated series. Certain Medicare Advantage plans and healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to series of Series 44. As such, Series 44 has the right and power to sue Defendant to recover the payments at issue in this action.

53. Plaintiff MSP Recovery Claims, Series LLC (“MSPRC”), is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. MSPRC’s Amended and Restated Limited Liability Company Operating Agreement effective March 27, 2018, permits MSPRC to establish one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, MSPRC established various designated series to serve as units of the company to maintain various claims recovery assignments separate from other company assets, and to account for and associate certain assets with certain particular series.

54. MSPRC has enumerated rights relating to its designated series under its Amended and Restated Limited Liability Company Operating Agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c).

55. Specifically, all rights and benefits arising from assignments to its series (including the assignments discussed below) belong to MSPRC. MSPRC is authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series under its Amended and Restated Limited Liability Company Operating Agreement. MSPRC retained the legal right to sue on behalf of each designated series and pursue all rights, benefits, or causes of action arising from assignments to a series in its own name or in the name of the designated series. Certain Medicare Advantage plans and healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to series of MSPRC. As such, MSPRC has the right and power to sue Defendant to recover the payments at issue in this action.

56. Certain series of Series 44 and MSPRC (collectively, “MSP Plaintiffs”) have executed irrevocable assignments of any and all rights to recover payments made on behalf of their assigner’s health plan members and enrollees. These assignments authorize the series and, in turn, the MSP Plaintiffs through their Amended and Restated Limited Liability Company Operating Agreements, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. For purposes of giving examples, and only to serve to further demonstrate standing, the MSP Plaintiffs allege a few of the assignments below.

57. Effective April 28, 2016, Health First Health Plans, Inc. (“HFHP”), a Medicare Advantage organization, irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendant) for payments made on behalf of its enrollees under Medicare

Parts A, B, and D to MSP Recovery, LLC (the “HFHP Assignment”). The HFHP Assignment expressly provides, in pertinent part:

Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client’s right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto . . . all of which shall constitute the “Assigned Claims.”

The transfer, grant, right, or assignment of any and all of Client’s right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. This assignment is irrevocable and absolute.

58. On June 12, 2017, MSP Recovery, LLC, assigned all rights acquired under the HFHP Assignment to Series 16-05-456, a designated series of MSPRC (the “Series Assignment”).

The Series Assignment states:

[T]he undersigned Assignor . . . irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor’s right, title, ownership and interest in and to the Claims and Assigned Claims, (and all proceeds and products thereof, including any related assigned assets and assigned documents) as such terms are defined or contained in that certain (1) Assignment and (2) Addendum to the Recovery Agreement and Assignment Addendum, both given and effective April 28, 2016 and executed on June 1, 2018, by and between Health First Health Plans, Inc., a Florida corporation and Medicare Advantage Organization and party to contract number H1099 with The Centers for Medicare & Medicaid Services, as the “Client” and health plan assignor, and [MSP Recovery], a Florida limited liability company (the “Assignment”); irrespective of when the claims were vested in Client, inclusive of any and all claim(s), causes of actions, proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party pursuant to the Assignment from the Client, including claims under consumer protection statutes and laws, any and all rights and claims against

primary payers and/or third parties that may be liable to Client arising from or relating to the Claims and all information relating thereto.

59. Further, on October 22, 2020, Series 16-05-456 entered into an assignment agreement with Series 44-20-456, a designated series of Series 44, whereby it irrevocably assigned all rights it acquired through its assignment agreement with MSP Recovery, LLC. The assignment specifically states:

[Series 16-05-456] . . . hereby irrevocably assigns, transfers, conveys, sets over, and delivers to [Series 44-20-456] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to the [claims], as well as (ii) the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreements.

This Assignment includes all the Assigned Claims irrespective of when the claims were vested in HFHP, inclusive of any and all claim(s), causes of actions, proceeds, products, and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to HFHP arising from or relating to the Claims and all information relating thereto.

60. On May 30, 2019, Blue Cross & Blue Shield of Rhode Island ("BCBSRI") entered into a Statement of Work and Claims Purchase Agreement & Assignment with MSP Recovery, LLC, whereby it irrevocably assigned to MSP Recovery, LLC, all of its rights and claims to recovery against any liable entity (including Defendant) for payments made on behalf of its enrollees under Medicare Parts A, B, and D (the "BCBSRI Assignment"). The BCBSRI Assignment specifically states:

Client irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to (i) all Claims for which it has sent claims data to MSP Recovery, LLC, whether based in contract, tort or statutory right, and all related to recovery rights arising from and related all claims data transferred to MSP Recovery, LLC, and (ii) any and all causes of action, claims and demands of whatsoever nature relating to payments for healthcare services provided to Client's

members and enrollees, and related legal or equitable rights (including, but not limited to, subrogation) to pursue and/or recover monies related to the Claims that Client had, may have had, or has asserted against any party in connection with the Claims and (iii) all causes of action, claims, rights and demands of whatsoever nature, legal or equitable, against primary payers, Responsible Parties and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws (all of the Claims and rights set forth in (i)-(iii), the “*Assigned Claims*”).

61. Thereafter, effective on June 10, 2019, MSP Recovery, LLC, irrevocably assigned all rights acquired under the BCBSRI Assignment to Series 16-05-461, a designated series of MSP Recovery Claims, Series LLC (the “Series Assignment”). The Series Assignment from MSP Recovery, LLC to Series 16-05-461 states:

The Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor’s right, title, ownership and interest in and to the “Claims” and “Assigned Claims”, and all proceeds and products thereof (collectively the “*Assigned Claims*”) as such terms are defined in the *Recovery Agreement*. This Assignment includes all the Assigned Claims irrespective of when the claims were vested in *BCBS Rhode Island*, inclusive of any and all claim(s), causes of actions, proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to *BCBS Rhode Island* arising from or relating to the Claims and all information relating thereto.

62. The BCBSRI Assignment contemplated that the parties would enter into a “stand-alone assignment document evidencing” the BCBSRI Assignment. Following the contemplated due diligence period, the stand-alone assignment became effective May 30, 2019, thereby approving and consenting to the Series Assignment and all rights contained therein, including all claims and reimbursement rights, to and in favor of MSPRC or any of its designated series, including but not limited to, Series 16-05-461.

63. Further, on October 22, 2020, Series 16-05-461 entered into an assignment agreement with Series 44-20-461, a designated series of Series 44, whereby it irrevocably assigned all rights it acquired through its assignment agreement with MSP Recovery, LLC. The assignment specifically states:

[Series 16-05-461] . . . hereby irrevocably assigns, transfers, conveys, sets over, and delivers to [Series 44-20-461] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to that Agreement, as well as (ii) the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreement.

This Assignment includes all the Assigned Claims irrespective of when the claims were vested in BCBSRI, inclusive of any and all claim(s), causes of actions, proceeds, products, and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to BCBSRI arising from or relating to the Claims and all information relating thereto.

64. On March 20, 2018, Group Health Incorporated and Health Insurance Plan of Greater New York (otherwise known as "EmblemHealth" or "Emblem") irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendant) for payments made on behalf of their enrollees under Medicare Parts A, B, and D to Series 16-08-483, a designated series of MSPRC (the "Emblem Assignments"). The Emblem Assignments specifically state:

Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

65. On May 12, 2017, Summacare, Inc. (“Summacare”), irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP Recovery, LLC (the “Summacare Assignment”). The Summacare Assignment specifically states:

[Summacare] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [Summacare’s] right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [Summacare] that [Summacare] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [Summacare] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the “Assigned Claims”.

66. On June 12, 2017, MSP Recovery, LLC, irrevocably assigned all rights acquired under the Summacare Assignment to Series 16-11-509, a designated series of MSPRC:

[Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor’s right, title, ownership and interest in and to the [claims] (and all proceeds and products thereof) as such terms are defined in the Recovery Agreement dated May 12, 2017, by and among [Summacare] . . . and [MSP Recovery]

Summacare consented to, acknowledged, approved, and ratified the assignment from MSP Recovery, LLC to Series 16-11-509, which is memorialized in a letter dated September 5, 2018.

67. On March 20, 2018, Connecticare, Inc. (“Connecticare”), irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to Series 15-09-157, a designated series of MSPRC (the “Connecticare Assignment”). The Connecticare Assignment specifically states:

Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor’s right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to,

subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

68. On October 8, 2015, Healthcare Alliance Group, Inc. (“HAI”), irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendant) for payments made on behalf of its enrollees pursuant to Medicare law to MSP Recovery 15-475, LLC. Specifically, the HAI Assignment states the following:

[HAI] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, or its assigns, in perpetuity, any and all of [HAI’s] right, title, ownership and interest in and to all rights and entitlements, and all information and data used to pursue and/or recover monies for [HAI] that [HAI] has, may have had, or has asserted against any party including, but not limited to primary payors and/or third parties that may be liable to [HAI] arising from or relating to the Assigned Claims.

HAI Assignment at 1.1.

69. On June 12, 2017, MSP Recovery 15-475, LLC, irrevocably assigned all rights acquired under the HAI Assignment to Series 15-09-273, LLC, a designated series of MSPRC:

[Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor’s rights, title, ownership and interest in and to the [claims] (and all proceeds and products thereof) as such terms are defined in the Health Care Claim(s) Cost Recovery Agreement dated October 8, 2015, by and among [HAI] and MSP Recovery 15-475, LLC . . .

70. Consideration was given between each party in executing these assignments.

71. Defendant has manufactured and distributed Chantix throughout the United States, for which consumers made co-payments, and TPPs either paid or reimbursed. On information and belief, the MSP Plaintiffs’ payments include those payments for Defendant’s VCDs, which were also manufactured, distributed, and sold during that same period.

72. MSP Plaintiffs’ assignors purchased or paid in whole or in part for VCD drugs for their beneficiaries, which reside in the following states and territories: Alabama, Arizona,

California, Colorado, Connecticut, Florida, Georgia, Iowa, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Maine, Maryland, Michigan, Mississippi, Missouri, Nebraska, New Hampshire, North Carolina, New Jersey, New York, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin. Beneficiaries of the MSP Plaintiffs purchased VCDs during the Class Period for personal use. The MSP Plaintiffs' assignors are ultimately at risk and responsible for reimbursing or paying for beneficiaries' purchases of prescription drugs. The MSP Plaintiffs' assignors paid more for VCDs than they would have absent Defendant's misconduct.

73. For example, and only to further demonstrate standing, the MSP Plaintiffs allege some example payments made by its assignors for the VCDs in the table below. In each instance, one of MSP Plaintiffs' assignors received a request to reimburse a prescription drug on behalf of an enrollee for a particular date of service indicated below. The assignors paid the amounts indicated for contaminated, FDA-recalled lots of VCDs. To be clear, the table below does not demonstrate all of the MSP Plaintiffs' assignors' payments for VCDs, let alone all of the MSP Plaintiffs' damages.

Plaintiff Entity	Assignor	Assignor's Enrollee¹¹	Date of Service	Amount Paid	Member State
Series 44	HFHP	Patient A	7/14/2020	\$433.81	GA
Series 44	HFHP	Patient B	5/14/2020	\$463.78	FL
Series 44	HFHP	Patient C	9/3/2020	\$432.90	TN
MSPRC	Summacare	Patient D	9/16/2019	\$401.11	OH
MSPRC	Emblem	Patient E	2/27/2017	\$281.69	NY
Series 44	BCBSRI	Patient F	10/20/2017	\$398.63	RI
MSPRC	Emblem	Patient G	8/30/2016	\$342.45	NY
MSPRC	Connecticare	Patient H	6/17/2016	\$220.90	CT
MSPRC	HAI	Patient I	11/13/2018	\$196.80	IA
MSPRC	HAI	Patient J	9/26/2018	\$397.54	IL

¹¹ To ensure that this Complaint complies with federal law under the Health Insurance Portability and Accountability Act ("HIPAA"), the individual enrollees are referred to by these pseudonyms.

MSPRC	HAI	Patient K	11/13/2018	\$390.25	IN
MSPRC	HAI	Patient L	10/27/2018	\$389.91	MI
MSPRC	HAI	Patient M	5/18/2018	\$394.38	MO
MSPRC	HAI	Patient N	6/27/2018	\$213.35	NC
MSPRC	HAI	Patient O	9/9/2016	\$498.83	NE
MSPRC	HAI	Patient P	4/18/2017	\$341.37	TX
MSPRC	HAI	Patient Q	5/23/2018	\$419.36	WA
MSPRC	Summacare	Patient R	3/8/2016	\$249.63	AZ
Series 44	BCBSRI	Patient S	1/8/2020	\$404.29	MA
Series 44	BCBSRI	Patient T	1/9/2017	\$301.58	ME
MSPRC	Connecticare	Patient U	1/9/2017	\$328.64	NC
MSPRC	Emblem	Patient V	1/16/2016	\$187.84	NJ
MSPRC	Connecticare	Patient W	7/10/2014	\$150.84	PA
MSPRC	Connecticare	Patient X	6/17/2016	\$220.91	SC
Series 44	HFAP	Patient Y	9/3/2020	\$432.90	TN
MSPRC	Emblem	Patient Z	2/25/2013	\$103.95	VA
MSPRC	Summacare	Patient AA	11/19/2015	\$777.00	WV
Series 44	BCBSRI	Patient AB	7/25/2017	\$327.00	VT

74. Plaintiff Ohio Carpenters' Health Fund ("Ohio Carpenters'") is located in Troy, Michigan. Ohio Carpenters' is a tax-exempt IRC Section 501(c)(9) Voluntary Employee Benefit Association. Ohio Carpenters' is also a multiemployer, collectively bargained trust fund established in accordance with LMRA §302(c)(5), 29 U.S.C. §186(c)(5), for the purpose of providing benefits for employees and its beneficiaries. Ohio Carpenters' provides healthcare benefits to Participants and their eligible dependents (collectively, "beneficiaries"). Ohio Carpenters' insured beneficiaries are located throughout the United States. Plaintiff Ohio Carpenters' also operates a self-funded health insurance plan and workers' compensation plan for its employees and retirees and directly pays for all or a portion of its insureds' (including employees and dependents) healthcare costs, including but not limited to prescription costs.

75. Ohio Carpenters purchased or paid in whole or in part for VCD drugs for its beneficiaries throughout the United States, including the following states: Alabama, California, Florida, Indiana, Kentucky, Michigan, Missouri, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, West Virginia, and Wisconsin. Beneficiaries of Ohio Carpenters' purchased VCDs during the Class Period for personal use. Ohio Carpenters is ultimately at risk and responsible for reimbursing or paying for beneficiaries' purchases of prescription drugs. Ohio Carpenters paid more for VCDs than it would have absent Defendant's misconduct.

76. For example, and only to further demonstrate standing, Ohio Carpenters' alleges some exemplar payments for the VCDs in the table below. In each instance, Ohio Carpenters' received a request to reimburse a prescription drug on behalf of an enrollee for a particular date of service indicated below. Ohio Carpenters' paid the amounts indicated for contaminated, non-cGMP compliant, FDA-recalled lots of VCDs. The table below represents a portion of the payments made by Ohio Carpenters' and does not demonstrate all of Ohio Carpenters' payments for VCDs, let alone all of Ohio Carpenters' damages.

DATE	COST	NDC	LABEL NAME	DOSAGE
1/9/2019	\$392.92	00069046903	CHANTIX	1 MG
2/19/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
2/19/2019	\$412.54	00069046903	CHANTIX	1 MG
3/6/2019	\$441.97	00069046956	CHANTIX	1 MG
3/18/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
5/15/2019	\$318.25	00069047103	CHANTIX	0.5 (11)-1
5/15/2019	\$221.24	00069046856	CHANTIX	0.5 MG
5/15/2019	\$441.97	00069046956	CHANTIX	1 MG
5/29/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
6/8/2019	\$412.54	00069046903	CHANTIX	1 MG
6/11/2019	\$441.97	00069046956	CHANTIX	1 MG
6/17/2019	\$385.73	00069047103	CHANTIX	0.5 (11)-1
6/17/2019	\$385.73	00069046903	CHANTIX	1 MG
6/17/2019	\$441.97	00069046956	CHANTIX	1 MG
6/28/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1

7/8/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
7/30/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
8/5/2019	\$242.60	00069047103	CHANTIX	0.5 (11)-1
8/6/2019	\$1,167.32	00069046956	CHANTIX	1 MG
8/20/2019	\$412.54	00069046903	CHANTIX	1 MG
9/18/2019	\$375.82	00069047103	CHANTIX	0.5 (11)-1
10/14/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
10/21/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
11/14/2019	\$415.13	00069046956	CHANTIX	1 MG
11/18/2019	\$412.54	00069047103	CHANTIX	0.5 (11)-1
12/9/2019	\$412.54	00069046903	CHANTIX	1 MG
1/15/2020	\$433.15	00069047103	CHANTIX	0.5 (11)-1
2/6/2020	\$464.05	00069046956	CHANTIX	1 MG
3/5/2020	\$204.91	00069047	CHANTIX	0.5 (11)-1
3/11/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
3/17/2020	\$464.05	00069046	CHANTIX	1 MG
4/18/2020	\$433.15	00069046	CHANTIX	1 MG
5/31/2020	\$433.15	00069046	CHANTIX	1 MG
7/7/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
7/30/2020	\$400.60	00069047	CHANTIX	0.5 (11)-1
8/18/2020	\$408.42	00069046	CHANTIX	1 MG
9/15/2020	\$408.42	00069046	CHANTIX	1 MG
9/25/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/1/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/9/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/13/2020	\$433.15	00069046	CHANTIX	1 MG
10/13/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/13/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/26/2020	\$406.24	00069047	CHANTIX	0.5 (11)-1
11/10/2020	\$408.42	00069046	CHANTIX	1 MG
11/17/2020	\$464.05	00069046	CHANTIX	1 MG
11/24/2020	\$437.37	00069046	CHANTIX	1 MG
12/16/2020	\$464.05	00069046	CHANTIX	1 MG
12/17/2020	\$433.15	00069046	CHANTIX	1 MG
12/26/2020	\$464.05	00069046	CHANTIX	1 MG
1/5/2021	\$440.56	00069047	CHANTIX	0.5 (11)-1
1/6/2021	\$472.00	00069046	CHANTIX	1 MG
1/8/2021	\$440.56	00069047	CHANTIX	0.5 (11)-1
1/19/2021	\$440.56	00069046	CHANTIX	1 MG
2/19/2021	\$440.56	00069046	CHANTIX	1 MG
3/22/2021	\$440.56	00069046	CHANTIX	1 MG
4/16/2021	\$361.06	00069047	CHANTIX	0.5 (11)-1
4/27/2021	\$440.56	00069047	CHANTIX	0.5 (11)-1
4/27/2021	\$440.56	00069046	CHANTIX	1 MG
5/14/2021	\$1,089.34	00069046	CHANTIX	1 MG

1/9/2019	\$392.92	00069046	CHANTIX	1 MG
2/19/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
2/19/2019	\$412.54	00069046	CHANTIX	1 MG
3/6/2019	\$441.97	00069046	CHANTIX	1 MG
3/18/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
5/15/2019	\$318.25	00069047	CHANTIX	0.5 (11)-1
5/15/2019	\$221.24	00069046	CHANTIX	0.5 MG
5/15/2019	\$441.97	00069046	CHANTIX	1 MG
5/29/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
6/8/2019	\$412.54	00069046	CHANTIX	1 MG
6/11/2019	\$441.97	00069046	CHANTIX	1 MG
6/17/2019	\$385.73	00069047	CHANTIX	0.5 (11)-1
6/17/2019	\$385.73	00069046	CHANTIX	1 MG
6/17/2019	\$441.97	00069046	CHANTIX	1 MG
6/28/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
7/8/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
7/30/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
8/5/2019	\$242.60	00069047	CHANTIX	0.5 (11)-1
8/6/2019	\$1,167.32	00069046	CHANTIX	1 MG
8/20/2019	\$412.54	00069046	CHANTIX	1 MG
9/18/2019	\$375.82	00069047	CHANTIX	0.5 (11)-1
10/14/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
10/21/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
11/14/2019	\$415.13	00069046	CHANTIX	1 MG
11/18/2019	\$412.54	00069047	CHANTIX	0.5 (11)-1
12/9/2019	\$412.54	00069046	CHANTIX	1 MG
1/15/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
2/6/2020	\$464.05	00069046	CHANTIX	1 MG
3/5/2020	\$204.91	00069047	CHANTIX	0.5 (11)-1
3/11/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
3/17/2020	\$464.05	00069046	CHANTIX	1 MG
4/18/2020	\$433.15	00069046	CHANTIX	1 MG
5/31/2020	\$433.15	00069046	CHANTIX	1 MG
7/7/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
7/30/2020	\$400.60	00069047	CHANTIX	0.5 (11)-1
8/18/2020	\$408.42	00069046	CHANTIX	1 MG
9/15/2020	\$408.42	00069046	CHANTIX	1 MG
9/25/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/1/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/9/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/13/2020	\$433.15	00069046	CHANTIX	1 MG
10/13/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/13/2020	\$433.15	00069047	CHANTIX	0.5 (11)-1
10/26/2020	\$406.24	00069047	CHANTIX	0.5 (11)-1

11/10/2020	\$408.42	00069046	CHANTIX	1 MG
11/17/2020	\$464.05	00069046	CHANTIX	1 MG
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12/26/2020	\$464.05	00069046	CHANTIX	1 MG
1/5/2021	\$440.56	00069047	CHANTIX	0.5 (11)-1
1/6/2021	\$472.00	00069046	CHANTIX	1 MG
1/8/2021	\$440.56	00069047	CHANTIX	0.5 (11)-1
1/19/2021	\$440.56	00069046	CHANTIX	1 MG
2/19/2021	\$440.56	00069046	CHANTIX	1 MG
3/22/2021	\$440.56	00069046	CHANTIX	1 MG
4/16/2021	\$361.06	00069047	CHANTIX	0.5 (11)-1
4/27/2021	\$440.56	00069047	CHANTIX	0.5 (11)-1
4/27/2021	\$440.56	00069046	CHANTIX	1 MG
5/14/2021	\$1,089.34	00069046	CHANTIX	1 MG

Defendant Pfizer

77. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer on its own or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Pfizer has been engaged in the manufacturing, sale, or distribution of Chantix and adulterated and misbranded VCDs in the United States. Pfizer manufactures the active pharmaceutical ingredient (“API”) for VCDs in Ireland and manufactures the finished-dose product incorporating that API in Germany and Italy.

78. Defendant has manufactured and distributed Chantix throughout the United States, for which consumers made co-payments, and TPPs either paid or reimbursed. On information and belief, Plaintiffs’ payments include those payments for Defendant’s VCDs, which were also manufactured, distributed, and sold during that same period.

JURISDICTION AND VENUE

79. This Court has federal subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendant, (b) the amount in controversy exceeds \$5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

80. This Court has personal jurisdiction over Defendant under 28 U.S.C. § 1407, and because Defendant is headquartered in New York, has sufficient minimum contacts in New York, and because Defendant has otherwise intentionally availed itself of the markets within the State of New York through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

81. Venue is proper in this District because at least some of the class's claims alleged in this action accrued in this District and Defendant regularly transacts its affairs in this District.

FACTUAL ALLEGATIONS

I. Background

A. Prescription Drug Reimbursement

82. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

83. Pharmaceutical manufacturers produce drugs that they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

84. TPPs contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in

coverage at various pricing “tiers”), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing drugs, such as Chantix, on the TPPs’ formularies.

85. In managing formularies, TPPs and their PBMs reasonably expect that branded prescription drugs reimbursable on their formularies are the same as the respective FDA-approved branded drugs. The TPPs permitted Chantix, and VCDs, to be included on their formularies based on the Defendant’s misrepresentations that their VCDs were bioequivalent and the same as FDA-approved branded Chantix, complied with all current Good Manufacturing Practices (“cGMPs”), and were safe for consumption.

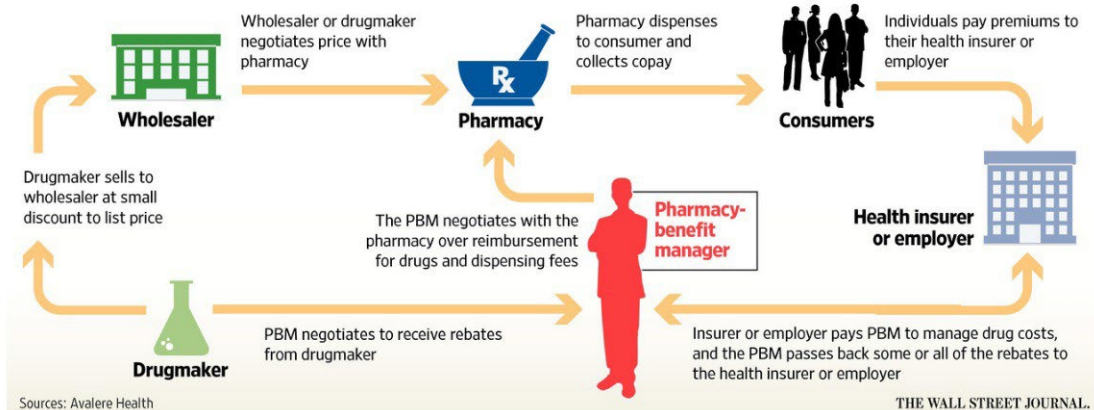
86. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co-payment, and the higher likelihood that plan beneficiaries will purchase the drug instead of a more expensive alternative. As a result, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs’ formularies to providers, pharmacists, and patients in their network to aid prescribers’ adherence to the formulary.

87. The following chart, published by the Wall Street Journal,¹² broadly illustrates the pharmaceutical supply chain:

¹² Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016), <https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336>.

How Drug Distribution Works

A complex supply chain determines how prescription drugs are paid for in the U.S.



88. When patients present their prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBM for reimbursement. PBMs then accumulate those individual reimbursements and present them to TPPs for payment.

B. Prescription Drug Product Identification and Tracing

89. For each approved product (whether brand or generic) the FDA issues a unique 10-digit code (the National Drug Code, or NDC) that follows the product from manufacturing through retail dispensing. The NDC embeds details about the specific product, including the identity of the manufacturer (or labeler), the strength, dosage form, and formulation of the drug, and the package size and type.¹³

90. The NDC is a critical component of each and every transfer of a prescription drug (from the manufacturer to the wholesaler; from the wholesaler to the retailer; and from the retailer to the consumer) and, therefore, every transaction is accompanied by and labeled with the NDC.

¹³ *National Drug Code Directory*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>; *National Drug Codes Explained*, DRUGS.COM, <https://www.drugs.com/ndc.html>.

This same code is used by TPPs in the real-time claims adjudication process to identify the precise dollar amount they will reimburse the pharmacy for a particular prescription drug purchase.

91. Retail prescription labels display the NDC of the dispensed product, which is part of the electronic dispensing record. In many cases, the “lot” number will also appear on the prescription bottle provided to the consumer and, thus, specifically indicate whether the recall applies to the particular pills in the bottle.¹⁴

92. The lot number is also used to report issues arising around a particular drug. For example, lot numbers are used by pharmacists to report Adverse Events (“AE”) (that is, patient-specific side effects or complications associated with the use of a prescription drug). This is an important part of drug safety monitoring in the United States and has led to recalls or relabeling of numerous drugs. Pharmacists make such reports using the FDA’s MedWatch system using Form 3500.¹⁵

C. The Drug Supply Chain Security Act Requires Tracing of Product

93. The Drug Supply Chain Security Act (“DSCSA”)¹⁶ was enacted in 2013, and requires prescription drug manufacturers, wholesalers, repackagers, and pharmacies to “[e]xchange information about a drug and who handled it each time it is sold in the U.S. market.”

¹⁴ A lot number is an identification number tied to a particular lot of pills from a single manufacturer.

¹⁵ *Instructions for Completing Form FDA 3500*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500#Section%20B:%20Adverse%20Event%20or%20Product%20Problem>.

¹⁶ 21 U.S.C. § 360eee.

94. The DSCSA was implemented as one part of the Drug Quality and Security Act (“DQSA”), aimed at addressing vulnerabilities in the drug supply chain, and facilitating tracing of certain prescription drugs in finished dosage form through the supply chain.¹⁷

95. While the DSCSA was enacted in 2013, participants in the pharmaceutical supply chain maintained similar information as a part of their ordinary course of business prior to the enactment of the DSCSA.

96. The DSCSA generally requires participants in the drug supply manufacturing chain (starting from the manufacturer, through the wholesaler, to the retail pharmacy) to retain, for every pharmaceutical drug transaction, the following information about that transaction: product name; National Drug Code; container size; number of containers; lot number; date of transaction; date of shipment; and name and address of the entity transferring ownership and taking ownership of the product.

97. The DSCSA requires that this data be kept in a manner to allow these authorized participants to respond within 48 hours to requests from appropriate federal or state officials—in the event of a recall or for the purpose of investigating suspect product or an illegitimate product—for the transaction history of the pharmaceutical product.¹⁸

98. The supply chain for distribution of prescription drugs in the U.S. is highly concentrated. This means that data obtained from a relatively small number of market participants

¹⁷ Daniel R. Levinson, *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, U.S. DEPT. HEALTH & HUM. SERVS., at 2 (Mar. 2018), <https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf>.

¹⁸ *Title II of the Drug Quality and Security Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>.

can provide detailed information about the large majority of Chantix and VCD sales, transfers, and prescription fills.

99. The entire process of reimbursing pharmacies and consumers for end-purchases depends on the ability to know the precise drug and packaging that was dispensed, as well as the manufacturer of that drug. This system has necessarily resulted in very high levels of data standardization in this industry. Although pharmacies maintain their own “pharmacy log” data reflecting dispensing, sales and return activity, the key elements are fundamentally similar.

100. Because pharmacies require similar information for their own tracking and inventory systems, and wholesalers sell to multiple pharmacy chains, the key elements are fundamentally the same.

101. Further, all pharmacies must use the basic data fields, definitions and formats provided in the Telecommunications Guidelines developed by the National Council for Prescription Drug Programs, the use of which was made mandatory in 2003 under regulations implementing the Health Insurance Portability and Accountability Act (HIPAA).¹⁹ Because of these HIPAA requirements, all of these inter-related systems (Manufacturers, Wholesalers, Retailers, and TPPs) use a common language to identify products.

102. As a general matter, for Medicare and Medicaid compliance, pharmacies typically keep prescription records for ten years.²⁰

¹⁹ 45 C.F.R. § 162.1802.

²⁰ 42 C.F.R. § 423.505(d).

103. A key part of the DSCSA is the requirement that “product tracing information should be exchanged” for each transaction and retained for at least six years,²¹ including the following transaction information (“TI”):²²

- a. Proprietary or established name or names of the product;
- b. Strength and dosage form of the product;
- c. National Drug Code (NDC) number of the product;
- d. Container size;
- e. Number of containers;
- f. Lot number of the product;
- g. Date of the transaction;
- h. Date of the shipment, if more than 24 hours after the date of the transaction;
- and
- i. Business name and address of the person from whom and to whom ownership is being transferred.

104. For example, the DSCSA also mandates use of a composite “product identifier” that Defendant was required to begin applying to prescription drug packages and cases.²³

²¹ *Protect Your Patients*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/113114/download>; 21 U.S.C. §§ 360eee-1(b)(1)(A)(ii), (c)(bb)(BB)(II)(v)(I), and (d)(1)(A)(iii).

²² *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements*, U.S. FOOD & DRUG ADMIN., at 8-9 (Sept. 2015), <https://www.fda.gov/media/93779/download>.

²³ *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry*, U.S. FOOD & DRUG ADMIN. (Sept. 2018), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifier-requirements-under-drug-supply-chain-security-act-compliance-policy-guidance>.

105. The term “product identifier” “means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier . . . the standardized numerical identifier, lot number, and expiration date of the product.”²⁴

106. Publicly available Guidelines published by AmerisourceBergen require that “each Prescription Drug lowest saleable unit” it receives from a manufacturer must have the clearly indicated product identifier on the unit label.²⁵ In addition, case labels and partial case labels must list the lot number and expiration date.²⁶ The Guidelines illustrate these requirements as reproduced below.

AmerisourceBergen Manufacturer Labeling Requirements²⁷



DSCSA RX Serialized Unit Label

²⁴ 21 U.S.C. § 360eee(14).

²⁵ *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, AMERISOURCEBERGEN, at 14 (Jan. 2019), <https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf>.

²⁶ *Id.* at 15-16.

²⁷ *Id.* at 14-16.



Example of Rx Serialized Homogenous Case Label



Example Partial Case Labeled with SSCC

D. The Drug Approval Framework

107. Brand drug companies submitting a New Drug Application (“NDA”) must demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

108. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new drug for sale and marketing in the United States.

109. An NDA is supposed to provide enough information to permit the FDA to decide (i) whether the drug is safe and effective for its proposed uses and whether the benefits of the drug outweigh the risks; (ii) whether the drug’s proposed labeling is appropriate and what it should contain; and (iii) whether the methods used in manufacturing the drug and the controls used to

maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.²⁸

110. As the FDA puts it, the submitted NDA documentation “is supposed to tell the drug's whole story,” including “what the ingredients of the drug are.”²⁹

111. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

112. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or, in other words, when the drug is not the same as its corresponding brand-name drug, the manufacturer may no longer rely on the drug's labeling.

113. A drug's labeling must “contain a summary of the essential scientific information needed for safe and effective use. . . [It] shall be informative and accurate and neither promotional in tone nor false and misleading[.]” 21 C.F.R. § 201.56.

E. Approval of the NDA for Chantix

114. Chantix is known generically as varenicline (as the tartrate salt) and is a partial nicotine agonist. It is a first-line therapy in the treatment to aid in smoking cessation. At a very high level, the drug works by interfering with the nicotine receptors in the human brain. This has the effect of lessening the pleasure a person gets from smoking or lessening the craving to smoke.

115. The FDA approved Chantix in May 2006. Pfizer later succeeded in extending its patent exclusivity for Chantix through August 2022, meaning Chantix has not faced generic drug competition since its launch.

²⁸ See, e.g., *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

²⁹ *Id.*

116. Chantix’s FDA-approved labeling specifies the active and inactive ingredients. Neither N-nitroso-varenicline nor N-Nitroso-dimethylamine (“NDMA”) nor any other nitrosamine is listed among the FDA- approved ingredients nor are any of these contaminants FDA-approved ingredients of Chantix.

117. Pfizer encountered a number of challenges during its clinical trials and regulatory submissions for Chantix. For example, Pfizer was alleged to have inadequately studied, evaluated, and tested Chantix during product development. *See generally In re Chantix (Varenicline) Products Liability Litigation (No. 1)*, MDL 2092, 09-cv-02039 (N.D. Ala.).

F. Drugs Must Be Manufactured in Compliance with Good Manufacturing Practices

118. Under federal law, pharmaceutical drugs must be manufactured in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

119. Moreover, 21 C.F.R. § 210.1(a) states that the cGMPs establish “minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.” In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

120. The FDA’s cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards for: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K).

The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

121. Under federal law, cGMPs include “the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.” 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors’ operations.

122. FDA regulations require a “quality control unit” to independently test drug product manufactured by another company on contract:

There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

123. Indeed, FDA regulations require a drug manufacturer to have “written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.” 21 C.F.R. § 211.100.

124. A drug manufacturer’s “[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.” 21 C.F.R. § 211.160.

125. “Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays” and a “statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.” 21 C.F.R. § 211.194.

G. Adulterated or Misbranded Drugs Are Illegal to Sell

126. Any drug not manufactured in accordance with cGMPs is deemed “adulterated and/or misbranded” or “misbranded” and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

127. Among the ways a drug may be adulterated or misbranded are:

- a. “if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health”;³⁰
- b. “if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess”;³¹

³⁰ 21 U.S.C. § 351(a)(2)(A).

³¹ 21 U.S.C. § 351(a)(2)(B).

- c. “If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls below, the standard set forth in such compendium”,³² or
- d. “If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.”³³

128. A drug is misbranded:

- a. “If its labeling is false or misleading in any particular”,³⁴
- b. “If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use”,³⁵
- c. If the labeling does not contain, among other things, “the proportion of each active ingredient”,³⁶
- d. “Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users”,³⁷
- e. “If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein”,³⁸

³² 21 U.S.C. § 351(b).

³³ 21 U.S.C. § 351(d).

³⁴ 21 U.S.C. § 352(a)(1).

³⁵ 21 U.S.C. § 352(c).

³⁶ 21 U.S.C. § 352(e)(1)(A)(ii).

³⁷ 21 U.S.C. § 352(f).

³⁸ 21 U.S.C. § 352(g).

- f. “if it is an imitation of another drug”;³⁹
- g. “if it is offered for sale under the name of another drug;”⁴⁰
- h. “If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof”;⁴¹
- i. If the drug is advertised incorrectly in any manner;⁴² or
- j. If the drug’s “packaging or labeling is in violation of an applicable regulation.”⁴³

129. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law.⁴⁴

130. The introduction into commerce of any adulterated or misbranded drug is also prohibited.⁴⁵

131. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.⁴⁶

132. Pfizer’s contaminated, unapproved VCDs were adulterated or misbranded, or both, for the reasons demonstrated above.

³⁹ 21 U.S.C. § 352(i)(2).

⁴⁰ 21 U.S.C. § 352(i)(3).

⁴¹ 21 U.S.C. § 352(j).

⁴² 21 U.S.C. § 352(n).

⁴³ 21 U.S.C. § 352(p).

⁴⁴ 21 U.S.C. § 331(g).

⁴⁵ 21 U.S.C. § 331(a).

⁴⁶ 21 U.S.C. § 331(c).

133. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that its state-law tort claims do not impose any additional obligations on Pfizer beyond what is already required of it under federal law.

II. The Drugs Purchased by Plaintiff Were Not Chantix, But Adulterated and Misbranded Varenicline-Containing Drugs, Not of the Same Quality

134. The FDA’s website provides the definition for a drug:

The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.⁴⁷

135. 21 C.F.R. § 210.3(b)(7) defines an “active ingredient” in a drug as “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.”⁴⁸

136. Accordingly, the FDA requires the submission of an NDA by manufacturers whenever a new active ingredient is added to a drug, as the drug has become a new and differing

⁴⁷ *Human Drugs*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/industry/regulated-products/human-drugs#drug>.

⁴⁸ 21 C.F.R. § 210.3(b)(7).

drug from those previously approved by the FDA. Absent such an application, followed by a review and approval by the FDA, the new drug remains a distinct, unapproved product.⁴⁹

137. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject VCDs) cannot have the same label as the brand-name drug, as the two products are no longer the same and do not share therapeutic equivalence (e.g., do not have the same safety profile).

138. At the very least and alternatively, drugs with differing and dangerous ingredients than brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.⁵⁰

139. Here, N-nitroso-varenicline and other nitrosamines resulted from the deficient manufacturing process of the VCDs, rendering the VCDs different than the FDA-approved version of Chantix. Importantly, N-nitroso-varenicline and other nitrosamines can cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, N-nitroso-varenicline and other nitrosamines are, by definition, an active ingredient in a drug.

140. Because the VCDs purchased or paid for by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs (i.e., never assessed the impact on the safety and efficacy profile of a product that contains nitrosamines).

⁴⁹ See 21 C.F.R. § 310.3(h).

⁵⁰ See generally *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA*, U.S. DEP'T JUST. (May 13, 2013), <https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false>.

141. The presence of additional active ingredients (N-nitroso-varenicline and other nitrosamines) and potentially other deviations from Defendant Pfizer's NDA rendered Defendant's VCDs of a lesser quality than FDA-approved Chantix.

142. A contaminated and adulterated VCD is not a substitute for FDA-approved Chantix and has no value to a purchaser of Chantix.

143. Plaintiffs and other Class Members paid or reimbursed for FDA-approved Chantix, but that is not what was received.

144. Plainly, Defendant did not deliver the product that Plaintiffs and Class Members paid or reimbursed for.

III. Defendant Made False Statements About Its VCDs

145. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended,"⁵¹ and conform to requirements governing the appearance of the label.⁵²

146. "Labeling" encompasses all written, printed, or graphic material accompanying the drug or device,⁵³ and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.

147. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."⁵⁴

⁵¹ 21 C.F.R. § 201.5.

⁵² 21 C.F.R. § 801.15.

⁵³ *See id.*

⁵⁴ *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

148. If a manufacturer labels a drug but omits ingredients and/or undisclosed risks, that renders the drug misbranded.⁵⁵

149. Because Pfizer did not disclose that its VCDs contained N-nitroso-varenicline or other nitrosamines as an ingredient, the subject drugs were misbranded.

150. In addition, by referring to its drugs as “Chantix,” Defendant was making false statements. While Pfizer was the NDA holder for FDA-approved Chantix, the VCDs it sold, and which Plaintiffs and other Class Members purchased, were a different, new unapproved drug not therapeutically equivalent to FDA-approved Chantix, on account of a different undisclosed safety profile, different identity, purity and quality, and not being made in a cGMP-compliant manner.

151. It is unlawful to introduce a misbranded drug into interstate commerce.⁵⁶ Thus, the Chantix products ingested by consumers (and paid for or reimbursed by TPPs) were unlawfully distributed and sold.

IV. Defendant Represented VCDs Were Manufactured in Compliance with Current Good Manufacturing Practices

152. Under federal law, cGMPs include “the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.” 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors’ operations.

153. FDA regulations require a “quality control unit” to independently test drug product manufactured by another company on contract:

⁵⁵ 21 C.F.R. §§ 201.6; 201.10.

⁵⁶ 21 U.S.C. § 331(a).

There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

154. Indeed, FDA regulations require a drug manufacturer to have “written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.” 21 C.F.R. § 211.100.

155. A drug manufacturer’s “[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.” 21 C.F.R. § 211.160.

156. “Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays” and a “statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.” 21 C.F.R. § 211.194.

157. Defendant’s VCDs did not conform with the NDA specifications, which demonstrates inadequate production, process, and quality oversight by Defendant.

158. Defendant’s failure to conform to cGMPs resulted in the production, and ultimate sale and reimbursement, of a product that was so contaminated and adulterated with high—not merely trace—levels of N-nitroso-varenicline that it could not be considered Chantix, yet Defendant still falsely labeled its products as FDA-approved Chantix.

V. Nitrosamines Are Dangerous, Genotoxic Carcinogens That Should Not Be in VCDs

159. Nothing in the FDA-approved NDA for Chantix indicated that nitrosamines are or might be present in the drug. That is, Chantix made according to the FDA-approved process, under appropriate quality oversight as required by cGMP, should not include any undisclosed nitrosamines.

160. Nitrosamines are semi-volatile chemicals that form during industrial and natural processes. Nitrosamines have no known, let alone FDA approved, therapeutic benefit.

161. The ICH M7 Guidance specifically refers to nitrosamines as being within the “cohort of concern,” comprised of high potency mutagenic carcinogens.⁵⁷ The Guidance teaches that dangerous compounds like nitrosamines should be characterized, and methods developed to eliminate or control them. Every iteration of the ICH M7 Guidance dating back to 2006 similarly classified nitrosamines and warned of the need for “compound-specific toxicity data” beyond that for other substances.⁵⁸

⁵⁷ *ICH Guidance for Industry, M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk*, U.S. FOOD & DRUG ADMIN. (Mar. 2018), <https://www.fda.gov/media/85885/download>. Earlier iterations of the ICH M7(R1) Guidance classified nitrosamines the same way.

⁵⁸ *See, e.g., ICH Guidance for Industry, M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk*, EUROPEAN MEDICINES AGENCY, at <https://www.ema.europa.eu/en/ich-m7-assessment-control-dna-reactive-mutagenic-impurities-pharmaceuticals-limit-potential#document-history-section> (collecting iterations of guidance back to issuance in 2006).

162. Agencies ranging from IARC and WHO,⁵⁹ to the EPA,⁶⁰ to the American Conference of Governmental Industrial Hygienists,⁶¹ to the Agency for Toxic Substances and Disease Registry⁶² to the U.S. Department of Health and Human Services (“DHHS”)⁶³ classify various nitrosamine compounds as probable human carcinogens.⁶⁴

163. Anecdotally, NDMA has also been used in intentional poisonings.⁶⁵

164. Nitrosamines are not new. The scientific community has been aware of nitrosamine formation and carcinogenicity for several decades. The chemical reactions leading to nitrosamine formation have been described as textbook chemistry.⁶⁶ The carcinogenicity of nitrosamines has been well documented since at least the 1950s.⁶⁷

⁵⁹ See, e.g., IARC Scientific Publications, No. 14, Lyon, France: International Agency for Research on Cancer, 1976; *Environmental Aspects of N-Nitroso Compounds*, Vol. 1. (E.A. Walker, M. Castegnaro, L. Gričute, and R.E. Lyle, eds.), IARC Scientific Publications, No. 19, Lyon, France: International Agency for Research on Cancer, 1978; *N-Nitroso Compounds: Analysis, Formation and Occurrence*. (E.A. Walker, M. Castegnaro, L. Gričute, and M. Borzsonyi, eds.), IARC Scientific Publications, No. 31, Lyon, France: International Agency for Research on Cancer, 1980.

⁶⁰ *Technical Fact Sheet N-Nitroso-dimethylamine (NDMA)*, U.S. ENVIRONMENTAL PROTECTION AGENCY (Nov. 2017), available at https://www.epa.gov/sites/production/files/2017-0/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Pharmacology and Toxicology Guidance for Industry, Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches*, U.S. FOOD & DRUG ADMIN. (Dec. 2018).

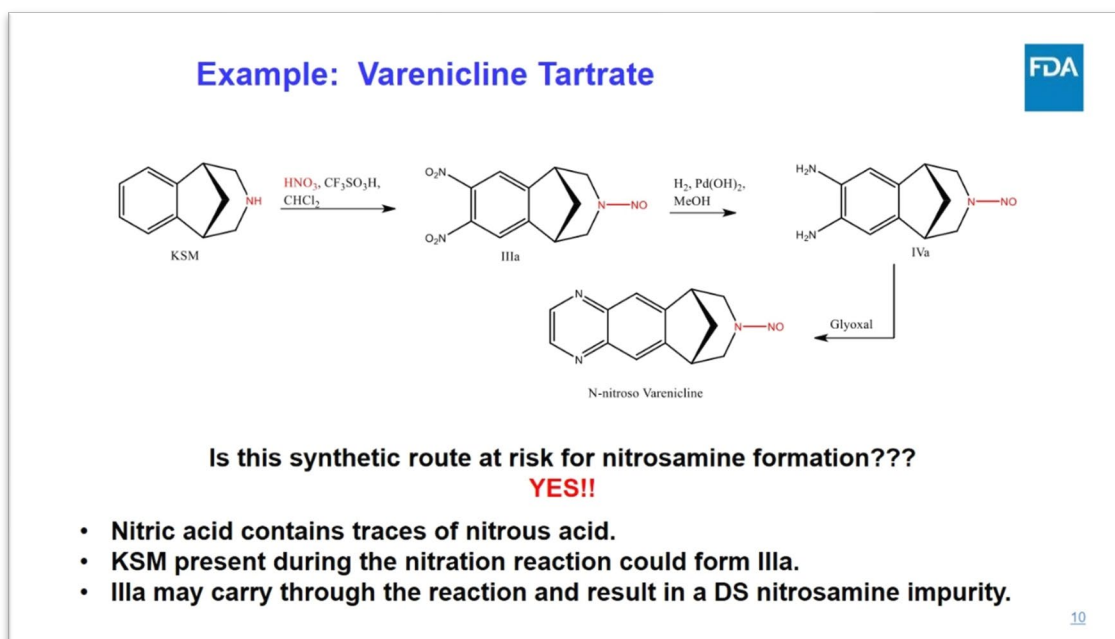
⁶⁵ See Chase Purde, *A common blood-pressure medicine is being recalled because of a toxic ingredient*, QUARTZ (July 18, 2018), <https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/>.

⁶⁶ Sun, Z., Liu Y.D., and Zhong, R.G. (2010) Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Trimethylamine, *J. Phys. Chem. A* 114, 455-465; 29; International Agency for Research on Cancer (1978); Some N-nitroso compounds, in *IARC Monogr. Eval. Carcinog. Risk Chem. Hum.* pp 83-175, IARC, Lyon, FR.

⁶⁷ Magee, P. N., and Barnes, J. M. (1956) The production of malignant primary hepatic tumors in the rat by feeding dimethylnitrosamine, *Brit J Cancer* 10, 114-122; see also, e.g., De Flora, S. et al., *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, *The Lancet*,

165. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as at least 2005,⁶⁸ and likely earlier. The scientific literature instructed for decades that companies should evaluate their products for the potential of nitrosamine formation.⁶⁹

166. The chemical reactions leading to the formation of N-nitroso-varenicline are no exception to this. As the FDA puts it:



167. The scientific literature also taught about nitroso compound formation in varenicline products for years prior to Defendant Pfizer's eventual VCD recalls in 2021.

Oct. 31, 1981, at 993-94; Maura, *et al.*, *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 *Tox. Ltrts.* 97-102 (1983); De Flora S., *et al.*, *Genotoxicity of Nitrosated Ranitidine*, 4 *Carcinogenesis* 3, 255-60 (1983).

⁶⁸ Lutz Müller *et al.*, *A rationale for determining, testing, and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity*, *REGUL. TOXICOLOGY & PHARMACOLOGY* (Dec. 26, 2005),

<https://www.sciencedirect.com/science/article/abs/pii/S0273230005002084?via%3Dihub>.

⁶⁹ *Id.*

168. Certainly, the entire pharmaceutical industry was acutely aware of nitrosamines in drug substance or drug product since at least mid-2018. Then, some of the largest drug product recalls in FDA’s history occurred concerning nitrosamine contamination of blood pressure medications valsartan, losartan, and irbesartan.⁷⁰ In the wake of those unprecedented recalls, the FDA explained that no level of nitrosamines were permissible in drugs.⁷¹ The FDA specifically advised the industry to be sure to evaluate their products for nitrosamines at that time, to the extent firms had not yet done so (which they should have been doing under ICH M7(R1) Guidance and other guidance and literature).⁷² Thus, Pfizer was on actual and constructive notice of the need to have adequate quality systems in place to detect, characterize, analyze, and quantify nitrosamines years before its VCD recalls in 2021. There is no indication that Pfizer ever undertook an appropriate evaluation of its VCDs to ascertain the likelihood of nitrosamine formation, let alone develop a cGMP-compliant way to avoid or at least minimize nitrosamine formations.

VI. Defendant’s VCDs Were Contaminated, Adulterated and Misbranded VCDs

169. In October 2020, Health Canada asked all companies marketing a varenicline product (including Pfizer) to evaluate and test their products for nitrosamines.⁷³

170. Pfizer’s own testing results provided to Health Canada showed undisclosed, impermissible N-nitroso-varenicline levels in Pfizer’s products.

⁷⁰ See generally, *FDA Updates and Press Announcements on Angiotension II Receptor Block (ARB) Recalls (Valsartan, Losartan, and Irbesartan)*, U.S. FOOD & DRUG ADMIN, at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan>.

⁷¹ *General Advice Ltr.*, U.S. FOOD & DRUG ADMIN. (2019) (“FDA has determined that there is no acceptable specification for nitrosamines . . . Therefore, FDA advises that nitrosamines should be absent[.]”), available at <https://www.fda.gov/media/122643/download>.

⁷² *Id.*

⁷³ *Champix (varenicline) – Potential Risk Posed by Long-Term Exposure to Nitrosamine Impurity, N-nitroso-varenicline, Exceeding Acceptable Intake Limits*, HEALTH CANADA (June 30, 2021), available at <https://recalls-rappels.canada.ca/en/alert-recall/champix-varenicline-potential-risk-posed-long-term-exposure-nitrosamine-impurity-n>.

171. Health Canada also confirmed the genotoxicity of N-nitroso-varenicline: “N-nitroso-varenicline has been shown to cause gene mutations in an in vitro study, indicating that its presence in CHAMPIX [the Canadian brand name for Chantix] may be associated with a potential increased cancer risk in humans.”⁷⁴

172. Despite the goings-on in Canada, Pfizer took no action in the United States for several months. Pfizer apparently did not begin testing and recalling its VCDs in the United States until July 2021. At that time, the FDA confirmed Pfizer’s VCD recalls were VCDs “because [the product] may contain levels of a nitrosamine impurity, called N-nitroso-varenicline, above FDA’s acceptable intake limit.”⁷⁵ Pfizer did not recall all its VCDs at the time.

173. According to the FDA’s testing in August 2021, Defendant Pfizer’s VCDs contained staggeringly high levels of N-nitroso-varenicline in the range of 155-474 parts per million. These results were *more than fifty times higher* than the levels the FDA detected in another company’s generic varenicline product.⁷⁶

174. Finally, in September 2021—nearly one year after Health Canada directly asked Pfizer and other companies to evaluate and test their varenicline products for nitrosamines—Pfizer extended its recall to all VCDs sold in the United States.⁷⁷ It has not reintroduced its VCDs into the market since.

⁷⁴ *Id.*

⁷⁵ *FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix>.

⁷⁶ *Laboratory analysis of varenicline products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-varenicline-products>.

⁷⁷ *Pfizer Expands Voluntary Nationwide Recall to include All Lots of CHANTIX® (Varenicline) Tablets Due to N-Nitroso Varenicline Content*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n>.

175. In the wake of Pfizer's recalls, the FDA has granted emergency approval to two other companies' generic versions of Chantix. These products are made in such a way that nitrosamines are not present or are below the FDA's new acceptable intake levels (note the levels of nitrosamines found in Pfizer's VCDs were so staggeringly high they would never pass the FDA new intake levels if Pfizer tried to sell its VCDs today). This demonstrates there is an appropriate, cGMP-compliant way to make varenicline products, but Defendant Pfizer chose not to do so.

VII. Defendant Pfizer's cGMP Violations and Other Wrongful Conduct Resulted in Its VCDs Being Adulterated, Misbranded, and/or Unapproved

176. If Defendant had not routinely disregarded the FDA's cGMPs, or had fulfilled its quality assurance obligations, Defendant would have identified the presence of these nitrosamine contaminants almost immediately. This is evident from the basic chemistry of nitrosamines, the longstanding scientific study and literature about nitrosamine formation and carcinogenicity, the industry guidance recommending the evaluation and testing for nitroso compounds, and the 2018 valsartan recalls, all as described above.

177. Industry and regulatory standards prior to and after the 2018 valsartan recalls called for firms such as Pfizer to have processes in place to detect, characterize, analyze, and quantify nitrosamines well before Pfizer either initiated its recalls of VCDs in the United States, or Health Canada's actions in October 2020.

178. Prior to initiating recalls in the United States, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

179. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

180. And, as shown above, Pfizer's quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

181. Also, as shown above, the quality control units for all of Pfizer's manufacturing were grossly deficient in fulfilling their responsibilities.

182. If these sampling-related and quality-control-related cGMPs were properly observed by Pfizer, the nitrosamine contamination in Pfizer's VCDs would have been discovered almost immediately, and Defendant was thus (at minimum) on constructive notice from the moment its VCDs became contaminated.

183. Pfizer's manufacturing facilities responsible for VCDs have a checkered regulatory history. For instance, its finished-dose product facility in Italy (one of the two facilities, along with one in Germany, that Pfizer claimed before a transferor court was responsible for VCDs), received an FDA Warning Letter in 2015 for "significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals . . . These violations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 351(a)(2)(B), in that methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administrated in conformity with, CGMP."

184. Among the cGMP deficiencies identified in the warning letter were failures to thoroughly investigate unexplained discrepancies or failures in batches or components to meet

specifications, failure to exercise appropriate controls over master production records and systems, failure to properly handle chromatography testing systems and controls, and inadequate laboratory records. Although the precise products mentioned are redacted in the warning letter, even if these observations did not directly relate to VCDs, they are certainly indicative and probative of Pfizer's lax approach to cGMP compliance as to some of the very same quality components that would be involved in the detection of nitrosamines in VCDs.

185. Defendant Pfizer knowingly, recklessly, or negligently introduced adulterated or misbranded VCDs containing dangerous amounts of nitrosamines into the U.S. market. It failed to recall its VCDs because it feared permanently ceding market share to competitors.

VIII. Defendant's Warranties and Fraudulent and Deceptive Statements to Purchasers Regarding Its VCDs

186. Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to purchasers about its adulterated or misbranded VCDs.

187. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" known as the Orange Book.⁷⁸ The Orange Book is a public document; Defendant sought and received the inclusion of its VCD products in the Orange Book upon approval of its NDAs.

188. Defendant's VCDs are accompanied by an FDA-approved label. By presenting purchasers with an FDA-approved VCD label, Defendant made representations and express or implied warranties of the "sameness" of its product to the Orange Book listed Chantix, and that its

⁷⁸ *Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels or were not adulterated or misbranded or misbranded.

189. The VCDs produced and sold by Defendant were not FDA-approved Chantix.

190. By introducing its VCDs into the United States marketed as “Chantix,” Defendant represented and warranted to purchasers that its VCDs are in fact the same as Chantix. Much of the drug supply chain, including the most critical components of that supply chain (for example, patients and purchasers) rely on these representations and warranties.

191. In addition, Defendant affirmatively misrepresented and warranted to purchasers through its websites, brochures, and other marketing or informational materials that its VCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products’ FDA-approved labels.

192. The presence of nitrosamines in Defendant’s VCDs: (1) renders Defendant’s VCDs equivalent (that is, not the same) to listed Chantix, thus breaching Defendant’s express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendant’s VCDs worthless (or alternatively, certainly worth less), thus breaching Defendant’s express warranties of sameness; and (3) results in Defendant’s VCDs containing an ingredient that is not also contained in the FDA-approved label, also breaching Defendant’s express warranty of sameness (and express warranty that the products contained the ingredients listed on Defendant’s FDA-approved label). Defendant willfully, recklessly, or negligently failed to ensure its VCDs’ labels and other advertising or marketing statements accurately conveyed information about its products.

193. The presence of nitrosamines in Defendant’s VCDs and serial and willful failures to comply with cGMPs and other shortcomings in Defendant’s drug manufacturing processes have resulted in Defendant’s VCDs being adulterated or misbranded.

194. At all relevant times, Defendant also impliedly warranted that its VCDs were merchantable and fit for their ordinary purposes.

195. Naturally, due to their status as probable human carcinogens as listed by both the IARC and others, nitrosamines are not FDA-approved ingredients in VCDs. The presence of nitrosamines or impurities in Defendant's VCDs means that Defendant Pfizer has violated implied warranties to Plaintiffs and Class Members. The presence of nitrosamines in Defendant's VCDs makes Defendant Pfizer's VCDs non-merchantable and not fit for its ordinary purposes, breaching Defendant's implied warranty of merchantability and/or fitness for ordinary purposes.

196. For these and other reasons, Defendant's VCDs are, therefore, adulterated, misbranded, or unapproved, and it was illegal for Defendant to have introduced or sold such VCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

197. Adulterated, misbranded, or unapproved VCDs contaminated with cancer-causing compounds, or manufactured in a non-cGMP compliant manner, are essentially worthless (or alternatively, certainly worth less). No reasonable purchaser (including Plaintiffs) would purchase (or reimburse for) these nitrosamine-laden VCDs. Nor could they, as adulterated, misbranded, or unapproved VCDs cannot be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, or unapproved VCDs were worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved VCDs do not possess the same safety and efficacy profiles as their branded equivalents. As such, the VCDs were not what they were supposed to be.

198. Because of the seriousness of the impurity—unsafe levels of a carcinogen—all or virtually all purchasers immediately stopped paying for the tainted drug products after receiving notice of the recall. And even in the absence of nitrosamines, the cGMP failures at Defendant

Pfizer's manufacturing plants meant its products were adulterated for lack of adequate quality assurances.

IX. Fraudulent Concealment and Tolling

199. Plaintiffs' and Class Members' causes of action accrued on the date the FDA announced the recall of Pfizer's VCDs. Each Plaintiff exercised reasonable diligence but could not discover the nitrosamine contamination or Pfizer's cGMP violations, each of which independently rendered its VCDs adulterated, misbranded, and a non-approved new drug, because Pfizer's wrongful acts were concealed from Plaintiffs and the public, and facts pertinent to same were within Pfizer's possession and control.

200. Alternatively, any statute of limitation or prescriptive period is equitably tolled because of fraudulent concealment. Pfizer affirmatively concealed from Plaintiffs and other Class Members its unlawful conduct. Defendant affirmatively strove to avoid disclosing its knowledge of its cGMP violations related to their VCDs, and of the fact that their VCDs were adulterated and/or misbranded and contaminated with nitrosamines and were not the same as the FDA-approved Chantix.

201. For instance, Pfizer did not reveal to the public that its VCDs contained nitrosamines or were otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to FDA-approved Chantix.

202. To the contrary, Pfizer continued to represent and warrant that its VCDs were actually "Chantix" when they were not the same as Chantix, and continued to sell its VCDs in the United States after the 2018 valsartan recalls (when industry focus on nitrosamines became especially acute, even though the industry and literature knew of nitrosamine formation much earlier), and also after Health Canada's actions in October 2020.

203. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinary diligence, Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendant Pfizer's false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the prices paid for Defendant's VCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

204. As a result of Pfizer's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and other Class Members exercised reasonable diligence by, among other things, promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable any complaint to be filed sooner.

CLASS ACTION ALLEGATIONS

205. Plaintiffs seek to represent a Nationwide Class under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:

Nationwide Class: All individuals and entities in the United States and its territories and possessions who paid any amount of money for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.

206. The Nationwide Class has two sub-classes:

All individuals in the United States and its territories and possessions who paid any amount of money for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.

All TPPs in the United States and its territories and possessions who paid any amount of money for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.

207. Plaintiffs allege additional sub-classes for all purchasers in each State, territory, or possession—or combinations of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment—that paid any amount of money out of pocket for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant (collectively, with the two sub-classes above, the “Subclasses”).

208. Collectively, the foregoing Nationwide Class and the Subclasses are referred to as the “Class.”

209. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendant and affiliated entities, and their employees, officers, directors, and agents; (c) Defendant’s legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

210. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

211. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

212. **Numerosity:** While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially hundreds of entities nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

213. **Existence and predominance of common questions of law and fact:** Common questions of law and fact exist as to all Class and Subclass Members and predominate over any

questions affecting individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

- a. Whether Defendant made express or implied warranties of “sameness” to Plaintiffs and Class Members regarding its VCDs;
- b. Whether Defendant’s VCDs were, in fact, the same as Chantix consistent with such express or implied warranties;
- c. Whether Defendant’s VCDs were contaminated with nitrosamines or similar contaminants;
- d. Whether Defendant’s VCDs containing nitrosamines or similar contaminants were adulterated or misbranded;
- e. Whether Defendant violated cGMPs regarding the manufacture of its VCDs;
- f. Whether Defendant falsely claimed that its VCDs were the same as Chantix and thus therapeutically interchangeable;
- g. Whether Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;
- h. Whether Plaintiffs and other Class Members have been injured as a result of each Defendant’s unlawful conduct, and the amount of their damages;
- i. Whether a common damages model can calculate damages on a class-wide basis;
- j. When Plaintiffs’ and Class Members’ causes of action accrued; and
- k. Whether Defendant fraudulently concealed Plaintiffs’ and Class Members’ causes of action.

214. **Typicality:** Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

215. **Adequacy of Representation:** Plaintiffs are committed to pursuing this action and has retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

216. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply generally to Class Members so that preliminary or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

217. **Superiority:** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against Defendant, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiffs'

counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

CAUSES OF ACTION

COUNT I **BREACH OF EXPRESS WARRANTIES**

218. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

219. Plaintiffs, and each member of the Class, formed a contract with Defendant at the time Plaintiffs and the other Class Members paid for the VCDs. The terms of the contract include the promises and affirmations of fact made by Defendant on the VCDs' packaging and through marketing and advertising, including that the product would be bioequivalent and therapeutically equivalent to and the same as FDA-approved Chantix, and would be of same "quality" and have the same safety and efficacy profile as FDA-approved Chantix. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain and are part of the standardized contract between Plaintiffs and the members of the Class and Defendant.

220. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's adulteration or misbranding. Defendant's distribution and sale of its VCDs was a direct affirmation that its VCDs were not adulterated, i.e., did not contain any nitrosamine contaminants, and were made in a cGMP-compliant manner. These affirmations were false.

221. Further, Defendant affirmed in its product labeling (e.g., label, package insert, medication guide) that its VCDs were therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Chantix. These affirmations were false. Defendant's VCDs did *not* have the same safety profile as FDA-approved Chantix. Undisclosed were the facts of

nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's VCDs further lacked the appropriate identity, quality, and purity. Defendants' VCDs were not safe as warranted, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

222. Defendant's product labeling (e.g., label, package insert, medication guide) were required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's VCD product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination and that the VCDs were not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

223. Defendant's sale of VCDs expressly warranted the products were compliant with compendial standards, USP requirements, Orange Book requirements. These affirmations were false, because Defendant's VCDs were not therapeutically equivalent to FDA-approved Chantix, with inter alia a different safety profile, different identity, purity, and quality characteristics, and not made in a cGMP-compliant manner.

224. Defendant expressly warranted that its VCDs were merchantable, and fit for ordinary use, as an FDA-approved pharmaceutical that is therapeutically equivalent to and the same as FDA-approved Chantix. In other words, Defendant expressly warranted that its products were the same as FDA-approved Chantix, in terms of therapeutic equivalence, safety profile, possessing the same identity, purity, and quality, and assurance of being made in a cGMP-compliant manner.

225. Defendant sold VCDs that it expressly warranted were compliant with cGMPs and were not adulterated or misbranded. Indeed, the very fact that Defendant sold VCDs in the stream

of commerce warranted they were cGMP-compliant and not adulterated because adulterated products are illegal to sell or dispense.

226. Defendant's VCDs did not conform to Defendant's express representations and warranties because the product was not manufactured in compliance with cGMPs, contained nitrosamine contaminants, was not therapeutically equivalent, lacked the same safety profile as FDA-approved Chantix, had different identity, purity, and quality characteristics, and were adulterated and misbranded.

227. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code

§ 8.2- 313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.

228. At the time that Defendant marketed and sold its VCDs, it recognized the purposes for which the products would be used, and expressly warranted the products were the same as FDA-approved Chantix, made in a cGMP-compliant manner, were not contaminated with nitrosamines, and were not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase or reimbursement by Plaintiffs and other Class Members including but not limited to express representations made in referring to its VCDs.

229. Plaintiffs and each member of the Class were reasonably expected purchasers who would use, consume or be affected by (or whose insureds would use, consume, or be affected by) the adulterated, misbranded, and sub-standard VCDs manufactured and sold by Defendant.

230. Defendant breached its express warranties with respect to its VCDs as they were not of merchantable quality, were not fit for their ordinary purpose, were contaminated with nitrosamines, did not comply with cGMPs and were adulterated and misbranded.

231. Plaintiffs and each member of the Class would not have (and could not have) paid for the VCDs had they known these drugs were not the same as FDA-approved Chantix, did not contain the same ingredients, did not have the same safety and efficacy profile of as FDA-approved Chantix, and contained nitrosamines. They did not receive the expected benefit of the bargain by receiving VCDs that contained undisclosed dangerous nitrosamines and/or were made in a non-cGMP compliant manner, either of which rendered the products adulterated, misbranded, illegal to sell, and therefore worthless (or alternatively, certainly worth less).

232. Defendant's VCDs did not fulfill their intended purpose. Plaintiffs and other Class Members bargained for an adequately made, adequately labeled product that did not pose

significant undisclosed risks. But Defendant's VCDs were not adequately made, were not adequately labeled, and posed significant undisclosed risks, viz., they contained an undisclosed genotoxic carcinogen. While Plaintiffs and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences.

233. As a direct and proximate result of Defendant's breach of express warranties, Plaintiffs and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, the lost value of any non-returned product rendered unusable after the recalls, and any consequential damages resulting from the purchases, in that the VCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

COUNT II **BREACH OF IMPLIED WARRANTIES**

234. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

235. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2- 314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md.

Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314; and Wyo. Stat. § 34.1-2-314.

236. Defendant was a merchant within the meaning of the above statutes.

237. Defendant's VCDs constituted "goods" or the equivalent within the meaning of the above statutes. Defendant placed their VCDs in sealed packaging or other closed containers and placed them on the market.

238. Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit VCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendant is involved such that the product was of fit and merchantable quality.

239. Defendant knew or should have known that its VCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to FDA-approved Chantix (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that its VCDs were of merchantable quality and fit for that purpose.

240. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's

adulteration or misbranding. Defendant's distribution and sale of its VCDs was an implied affirmation that its VCDs were not adulterated, i.e., did not contain any nitrosamine contaminants, and were made in a cGMP-compliant manner. These affirmations were false.

241. Further, Defendant impliedly affirmed in its product labeling (e.g., label, package insert, medication guide) that its VCDs were therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Chantix. These affirmations were false. Defendant's VCDs did *not* have the same safety profile as FDA-approved Chantix. Undisclosed were the facts of nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's VCDs further lacked the appropriate identity, quality, and purity. Defendant's VCDs were not safe as warranted, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

242. Defendant's product labeling (e.g., label, package insert, medication guide) were required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's VCD product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination and that the VCDs were not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

243. Defendant's sale of VCDs impliedly warranted that the products were compliant with compendial standards, USP requirements, and Orange Book requirements. These affirmations were false because Defendant's VCDs were not therapeutically equivalent to FDA-approved Chantix, with inter alia a different safety profile, different identity, purity, and quality characteristics, and not made in a cGMP-compliant manner.

244. Defendant impliedly warranted that its VCDs were merchantable, and fit for ordinary use, as an FDA-approved pharmaceutical that is therapeutically equivalent to and the same as FDA-approved Chantix. In other words, Defendant impliedly warranted that its products were the same as FDA-approved Chantix, in terms of therapeutic equivalence, safety profile, possessing the same identity, purity, and quality, and assurance of being made in a cGMP-compliant manner.

245. Defendant sold VCDs that it impliedly warranted were compliant with cGMPs and were not adulterated or misbranded. Indeed, the very fact Defendant sold VCDs in the stream of commerce warranted they were cGMP-compliant and not adulterated, because adulterated products are illegal to sell or dispense.

246. Defendant's VCDs did not conform to Defendant's implied representations and warranties because the product was not manufactured in compliance with cGMPs, contained nitrosamine contaminants, was not therapeutically equivalent, lacked the same safety profile as FDA-approved Chantix, had different identity, purity, and quality characteristics, and were adulterated and misbranded.

247. At the time that Defendant marketed and sold its VCDs, it recognized the purposes for which the products would be used, and impliedly warranted the products were the same as FDA-approved Chantix, made in a cGMP-compliant manner, were not contaminated with nitrosamines, and were not adulterated or misbranded. These implied representations became part of the basis of the bargain in every purchase or reimbursement by Plaintiffs and other Class Members including but not limited to implied representations made in referring to its VCDs.

248. Plaintiffs and each member of the Class were reasonably expected purchasers who would use, consume or be affected by (or whose insureds would use, consume, or be affected by) the adulterated, misbranded, and sub-standard VCDs manufactured and sold by Defendant.

249. Plaintiffs and each other Class Member were the intended third-party beneficiary recipients of all arrangements Defendant had with downstream resellers of Defendant's VCDs. Plaintiffs and each other Class Member were those whose benefit any promises, affirmations, or warranties were made by Defendant concerning the VCDs, as they were the intended end purchasers and end users (or, in the case of TPPs, their insureds were the intended end users) of Defendant's VCDs, which Defendant knew by virtue of its position as manufacturer and seller of the VCDs.

250. Defendant knew, or should have known, that its VCDs were being manufactured and sold for the intended purpose of human consumption as the therapeutic equivalent to FDA-approved Chantix, with the same safety profile, identity, purity, and quality characteristics, and manufactured in a cGMP-compliant manner.

251. Defendant breached its implied warranty because Defendant's VCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

252. Plaintiffs and other Class Members purchased the VCDs in reliance on Defendant's skill and judgment and the implied warranties of fitness for the purpose.

253. The VCDs were not altered by Plaintiffs or any other Class Members.

254. Plaintiffs and each member of the Class would not have (and could not have) purchased the VCDs had they known these drugs were not the same as FDA-approved Chantix, did not contain the same ingredients, did not have the same safety and efficacy profile as FDA-

approved Chantix, and contained nitrosamines. They did not receive the expected benefit of the bargain by receiving VCDs that contained undisclosed dangerous nitrosamines and/or were made in a non-cGMP compliant manner, either of which rendered the products adulterated, misbranded, illegal to sell, and therefore worthless (or alternatively, certainly worth less).

255. Defendant's VCDs did not fulfill their intended purpose. Plaintiffs and other Class Members bargained for an adequately made, adequately labeled product that did not pose significant undisclosed risks. But Defendant's VCDs were not adequately made, were not adequately labeled, and posed significant undisclosed risks, viz., they contained an undisclosed genotoxic carcinogen. While Plaintiffs and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences.

256. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, the lost value of any non-returned product rendered unusable after the recalls, and any consequential damages resulting from the purchases, in that the VCDs they paid for were so inherently flawed, unfit, or unmerchantable as to have no market value.

COUNT III
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301 *et seq.*

257. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

258. Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

259. Plaintiffs and other Class Members are “consumers” within the meaning of the Magnuson-Moss Warranty Act.

260. Defendant expressly or impliedly warranted its VCDs as alleged in the First and Second Causes of Action.

261. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and other Class Members were “damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief.” 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of themselves and the Class Members.

262. Defendant has not acted on the opportunity to cure its failure with respect to its warranted VCDs.

263. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys’ fees and expenses and pray for the same.

COUNT IV
FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND
CONCEALMENT)

264. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

265. Defendant affirmatively misrepresented material facts including, among other things, that its VCDs were therapeutically equivalent and the same as FDA-approved Chantix including per the Orange Book, that its VCDs were not a new unapproved drug, that its VCDs did not contain any undisclosed contaminants or risks, that its VCDs were manufactured in a cGMP-compliant manner, and that its VCDs were saleable and were not adulterated or misbranded.

266. Defendant omitted and/or affirmatively concealed material facts including, among other things, that its VCDs were not therapeutically equivalent or the same as FDA-approved Chantix including per the Orange Book, that its VCDs were not a new unapproved drug, that its VCDs did not contain any undisclosed contaminants or risks, that its VCDs were manufactured in a cGMP-compliant manner, and that its VCDs were saleable and were not adulterated or misbranded.

267. Defendant knew or should have known, prior to initiating its VCD recalls in the United States in 2021, about the risks posed by nitrosamine as a result of industry guidance, regulatory guidance, and the scientific literature dating back decades. Defendant certainly knew at least no later than July 2018 about the urgent need to properly evaluate and test products for nitrosamines in the wake of the valsartan recalls, or at least no later than October 2020 following Health Canada's actions. Defendant similarly knew or should have known prior to initiating its VCD recalls about that cGMP deviations or failures concerning quality control and risk management may result in the adulteration and misbranding of a drug product.

268. Defendant knew or should have known, or was deliberately indifferent to knowing, the chemistry relevant to its VCD manufacture process. Appropriate, cGMP-compliant evaluation, testing, quality oversight, and risk management would have identified the nitrosamine contaminants in Defendant's VCDs, which by virtue of its manufacturing process is reasonably expected to generate such contaminants in every batch or lot of VCDs, at levels beyond any applicable intake limit established by the FDA (the limit was zero prior to the FDA's interim limits, and even after that all testing available show that nitrosamine levels in Defendant's VCDs far exceeded those limits).

269. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's adulteration or misbranding. Defendant's distribution and sale of its VCDs was a direct affirmation that its VCDs were not adulterated, i.e., did not contain any nitrosamine contaminants, and were made in a cGMP-compliant manner. These affirmations were false.

270. Further, Defendant affirmed in its product labeling (e.g., label, package insert, medication guide) that its VCDs were therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Chantix. These affirmations were false. Defendant's VCDs did *not* have the same safety profile as FDA-approved Chantix. Undisclosed were the facts of nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's VCDs further lacked the appropriate identity, quality, and purity. Defendant's VCDs were not safe as represented, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

271. Defendant's product labeling (e.g., label, package insert, medication guide) were required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's VCD product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination and that the VCDs were not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

272. Defendant's sale of VCDs represented the products were compliant with compendial standards, USP requirements, and Orange Book requirements. These representations were false, because Defendant's VCDs were not therapeutically equivalent to FDA-approved

Chantix, with inter alia a different safety profile, different identity, purity, and quality characteristics, and not made in a cGMP-compliant manner.

273. Defendant's other promotional materials represented that VCDs were a safe therapy for smoking cessation without any undisclosed risks. For instance, in 2016, Pfizer video sponsorship ads featuring actor Ray Liotta touted Defendant's VCDs as safe and effective. Absent from the side effects, warnings, and precautions enunciated was any reference to the presence of genotoxic, carcinogenic nitrosamine contaminants. Similarly, in 2019 (after the 2018 valsartan recalls, which greatly heightened global industry's focus on nitrosamines), Pfizer's "slow turkey" ad made no mention of the presence of genotoxic, carcinogenic nitrosamine contaminants in the side effects, warnings, and precautions enunciated.

274. Defendant omitted from its product labeling, other promotional materials, and through its sale of VCDs that its VCDs contained a dangerous, undisclosed, genotoxic, carcinogenic nitrosamine, and that the VCDs were not made in a cGMP-compliant manner.

275. Defendant's product labeling (e.g., label, package insert, medication guide) and other promotional materials contained, at best, half-truths about the safety and cGMP compliance status of its VCDs. Once Defendant voluntarily chose to speak about its VCDs, it had a duty to do so truthfully. But it did not, given Defendant's knowledge of nitrosamine formation, its own VCD manufacturing process, and its own cGMP-compliance status. Failure to correct its statements rendered them untruthful.

276. Defendant knowingly, or at least recklessly, represented that its VCDs were manufactured in a cGMP manner and that its VCDs were what they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the

absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

277. Defendant's actions had the effect of fraudulently inducing Plaintiffs and other Class Members to pay in whole or in part for Defendant's VCDs—products which Defendant knew or should have known were not therapeutically equivalent to or the same as FDA-approved Chantix, contained undisclosed nitrosamines, were not made in a cGMP-compliant manner, and were adulterated or misbranded. Plaintiffs and other Class Members would not have paid for Defendant's VCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendant's VCDs had they known the truth because Defendant's VCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendant's fraudulent misrepresentations and omissions.

278. Defendant knew, or reasonably should have known, that its misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

279. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Plaintiffs and other Class Members to pay for some or all of the cost of Defendant's VCDs.

280. Defendant's misrepresentations and omissions were material.

281. Defendant actively concealed its misrepresentations and omissions from Plaintiff and other Class Members, government regulators, and the public.

282. To the extent applicable, Defendant intended its misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendant's VCDs.

283. But for these misrepresentations and omissions, Plaintiffs and other Class Members would not have paid for Defendant's VCDs.

284. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each Class Member, including through product labeling and other statements by Defendant. No reasonable consumer or TPP would have paid what they did for Defendant's VCDs but for Defendant's unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

285. Plaintiffs and each member of the Class would not have (and could not have) purchased the VCDs had they known these drugs were not the same as FDA-approved Chantix, did not contain the same ingredients, did not have the same safety and efficacy profile of as FDA-approved Chantix, and contained nitrosamines. They did not receive the expected benefit of the bargain by receiving VCDs that contained undisclosed dangerous nitrosamines and/or were made in a non-cGMP compliant manner, either of which rendered the products adulterated, misbranded, illegal to sell, and therefore worthless (or alternatively, certainly worth less).

286. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other.

287. This relationship arose because Defendant, as a pharmaceutical drug manufacturer owes a distinct duty to consumers of its highly-regulated pharmaceutical products, to be ingested by Plaintiffs and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its VCDs further bolstered the special relationship and distinct duty.

288. In addition, state drug regulation laws impose an independent duty on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health-General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);

- Montana Code §§ 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

289. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

290. Plaintiffs and other Class Members were damaged by reason of Defendant's misrepresentations and omissions as alleged here.

COUNT V
NEGLIGENT MISREPRESENTATION AND OMISSION

291. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

292. Defendant had or undertook a duty to represent the quality, nature, and characteristics of its VCDs accurately and truthfully.

293. Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its VCDs, namely representing that its VCDs were therapeutically equivalent to FDA-approved Chantix despite nitrosamine contamination and failure to manufacture the VCDs in compliance with cGMPs, rendering such representations false.

294. Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its VCDs, namely failing to disclose that its VCDs were not therapeutically equivalent to FDA-approved Chantix as result of nitrosamine contamination and failure to manufacture the VCDs in compliance with cGMPs.

295. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

296. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to pay or reimbursement for Defendant's VCDs.

297. Defendant knew or should have known prior to initiating recalls in the United States about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

298. Defendant knowingly, recklessly, or negligently represented that its VCDs were manufactured in a cGMP manner and that its VCDs were what they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

299. Defendant had direct or constructive knowledge of the risks of NDMA contamination at least as early as 2018 (and likely much sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, Defendant knew, and certainly should have known, of the possibility of nitrosamine formation in its VCDs, particularly because regulators including the FDA issued guidance in the second half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just like those used by Defendant to make its VCDs. Further, Health Canada specifically warned firms including Defendant about nitrosamine formation in VCDs in October 2020. Yet, Defendant sat by idly and did nothing in the United States until it began VCD recalls in the summer of 2021.

300. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that nitrosamine contamination occurred in VCDs potentially due to the similar route of contamination that resulted in nitrosamine

contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started three years before Defendant's recalls of its VCDs.

301. Thus, prior to initiating recalls of VCDs in the United States, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, Health Canada's actions in 2020, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about its VCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a cGMP compliant manner, each of which was false and either of which rendered the VCDs adulterated and misbranded.

302. Defendant's specific statements and omissions go beyond simply naming their VCDs "Chantix." Defendant's marketing and labeling carried with it the assurance, as required by state laws incorporating federal law, that the product did not contain any undisclosed contaminants, that VCDs had the same efficacy *and* safety profile as FDA-approved Chantix, and that the VCDs were not made in a non-cGMP compliant manner. Defendant omitted the material information that VCDs were not what they purported to be, insofar as they contained undisclosed dangerous nitrosamine contaminants, were not as safe as FDA-approved Chantix, and were not made in a cGMP-compliant manner. As such, the VCDs were adulterated and misbranded, which are illegal to sell. No Plaintiff or Class Member could ever buy an adulterated drug; thus, Defendant's distribution and sale of its VCDs in the first instance was a representation that the drugs were not adulterated.

303. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other.

304. This relationship arose because Defendant, as a pharmaceutical drug manufacturer owes a distinct duty to consumers of its highly-regulated pharmaceutical products, to be ingested by Plaintiffs and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its VCDs further bolstered the special relationship and distinct duty.

305. In addition, state drug regulation laws impose an independent duty on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);

- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and

- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

306. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

307. As a direct and proximate result of Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm and will continue to do so.

308. Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for VCDs.

309. Defendant intended its misrepresentations or omissions to induce Plaintiffs and Class Members to make purchases or reimbursements of VCDs or had reckless disregard for same.

310. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have made purchases of Defendant's VCDS.

311. Plaintiffs and other Class Members were justified in relying on Defendant's misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, or the same or substantively identical omissions were not communicated, to each Class Member.

312. Plaintiffs and other Class Members were damaged by reason of Defendant's misrepresentations or omissions alleged here.

COUNT VI
VIOLATION OF STATE CONSUMER PROTECTION LAWS

313. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

314. Defendant has violated the consumer protection statutes as follows:

- a. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;
- b. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;
- c. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;
- d. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;
- e. Defendant has violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;
- f. Defendant has violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;
- g. Defendant has violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*;
- h. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;
- i. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;
- j. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;
- k. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

- l. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;
- m. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-390, *et seq.* and §10-1-370, *et seq.*;
- n. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;
- o. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;
- p. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;
- q. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;
- r. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;
- s. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;
- t. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;
- u. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;
- v. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

- w. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;
- x. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;
- y. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;
- z. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;
- aa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;
- bb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;
- cc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;
- dd. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;
- ee. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;
- ff. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;
- gg. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

- hh. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;
- ii. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;
- jj. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, *et seq.*;
- kk. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;
- ll. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;
- mm. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;
- nn. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;
- oo. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;
- pp. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;
- qq. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;
- rr. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

- ss. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;
- tt. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;
- uu. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;
- vv. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;
- ww. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;
- xx. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;
- yy. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;
- zz. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;
- aaa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;
- bbb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and
- ccc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

315. Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

316. Defendant's VCDs are goods under the foregoing statutes, and Defendant is a merchant or seller.

317. Plaintiffs and other Class Members paid for VCDs for personal purposes, and each is an aggrieved person by virtue of Defendant's misconduct within the meaning of the above statutes.

318. Defendant, through a pervasive pattern of unfair, false, misleading, and deceptive statements and omissions, manufactured and sold VCDs without revealing to Plaintiffs and other Class Members that the products were not FDA-approved drugs, were not therapeutically equivalent to FDA-approved Chantix, were contaminated with nitrosamines, were not manufactured in accordance with cGMPs, posed significant undisclosed safety risks, and were adulterated and misbranded.

319. In addition to these material omissions, Defendant affirmatively and unfairly or deceptively misrepresented material facts including, that its VCDs were not new unapproved drugs, were therapeutically equivalent to FDA-approved Chantix, did not contain nitrosamines, were manufactured in accordance with cGMPs, did not carry any significant undisclosed safety risks, and were neither adulterated nor misbranded.

320. Defendant knew or should have known, prior to initiating its VCD recalls in the United States in 2021, about the risks posed by nitrosamine as a result of industry guidance, regulatory guidance, and the scientific literature dating back decades. Defendant certainly knew at least no later than July 2018 about the urgent need to properly evaluate and test products for nitrosamines in the wake of the valsartan recalls, or at least no later than October 2020 following

Health Canada's actions. Defendant similarly knew or should have known prior to initiating its VCD recalls that cGMP deviations or failures concerning quality control and risk management may result in the adulteration and misbranding of a drug product.

321. Defendant knew or should have known, or was deliberately indifferent to knowing, the chemistry relevant to its VCD manufacture process. Appropriate, cGMP-compliant evaluation, testing, quality oversight, and risk management would have identified the nitrosamine contaminants in Defendant's VCDs, which by virtue of its manufacturing process is reasonably expected to generate such contaminants in every batch or lot of VCDs, at levels beyond any applicable intake limit established by the FDA (the limit was zero prior to the FDA's interim limits, and even after that all testing available show that nitrosamine levels in Defendant's VCDs far exceeded those limits).

322. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's adulteration or misbranding. Defendant's distribution and sale of its VCDs was a direct affirmation that its VCDs were not adulterated, i.e., did not contain any nitrosamine contaminants, and were made in a cGMP-compliant manner. These affirmations were false.

323. Further, Defendant affirmed in its product labeling (e.g., label, package insert, medication guide) that its VCDs were therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Chantix. These affirmations were false. Defendant's VCDs did *not* have the same safety profile as FDA-approved Chantix. Undisclosed were the facts of nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's VCDs further lacked the appropriate identity, quality, and purity. Defendant's VCDs were not

safe as represented, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

324. Defendant's product labeling (e.g., label, package insert, medication guide) was required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's VCD product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination and that the VCDs were not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

325. Defendant's sale of VCDs represented the products were compliant with compliant with compendial standards, USP requirements, and Orange Book requirements. These representations were false because Defendant's VCDs were not therapeutically equivalent to FDA-approved Chantix, with inter alia a different safety profile, different identity, purity, and quality characteristics, and not made in a cGMP-compliant manner.

326. Defendant's other promotional materials represented that VCDs were a safe therapy for smoking cessation without any undisclosed risks. For instance, in 2016, Pfizer video sponsorship ads featuring actor Ray Liotta touted Defendant's VCDs as safe and effective. Absent from the side effects, warnings, and precautions enunciated was any reference to the presence of genotoxic, carcinogenic nitrosamine contaminants. Similarly, in 2019 (after the 2018 valsartan recalls, which greatly heightened global industry's focus on nitrosamines), Pfizer's "slow turkey" ad made no mention of the presence of genotoxic, carcinogenic nitrosamine contaminants in the side effects, warnings, and precautions enunciated.

327. Defendant omitted from its product labeling, other promotional materials, and through its sale of VCDs that its VCDs contained a dangerous, undisclosed, genotoxic, carcinogenic nitrosamine, and that the VCDs were not made in a cGMP-compliant manner.

328. Defendant's product labeling (e.g., label, package insert, medication guide) and other promotional materials contained, at best, half-truths about the safety and cGMP compliance status of its VCDs. Once Defendant voluntarily chose to speak about its VCDs, it had a duty to do so truthfully. But it did not, given Defendant's knowledge of nitrosamine formation, its own VCD manufacturing process, and its own cGMP-compliance status. Failure to correct its statements rendered them untruthful.

329. Defendant knowingly, or at least recklessly, represented that its VCDs were manufactured in a cGMP manner and that its VCDs were what they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

330. Defendant's actions had the effect of fraudulently inducing Plaintiffs and other Class Members to pay in whole or in part for Defendant's VCDs—products which Defendant knew or should have known were not therapeutically equivalent to or the same as FDA-approved Chantix, contained undisclosed nitrosamines, were not made in a cGMP-compliant manner, and were adulterated or misbranded. Plaintiffs and other Class Members would not have paid for Defendant's VCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendant's VCDs had they known the truth because Defendant's VCDs were

illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendant's fraudulent misrepresentations and omissions.

331. Defendant's conduct was unfair, deceptive, and unconscionable in that it included (i) the manufacture and sale of products with a heightened propensity to cause physical injuries and (ii) misrepresentations and omissions of material facts concerning the characteristics and safety of VCDs that offended public policy; was immoral, unethical, oppressive, outrageous, unscrupulous, and substantially injurious; and caused substantial harm that greatly outweighs any possible utility from the conduct.

332. Defendant's deliberate decision not to test the VCDs further constitutes unfair and unconscionable conduct. As set forth herein, the Defendant was aware of the risks that the VCDs were contaminated, misbranded and adulterated. Despite the risks to Plaintiffs and other Class Members, Defendant elected not to conduct risk assessment, quality analysis, and testing that would have prevented the Plaintiffs' exposure. The failure to ensure the safety of prescription drugs sold to consumers offends established public policy and constitutes immoral, unethical, oppressive, outrageous, unscrupulous, and substantially injurious conduct. The failure to test causes substantial harm to consumers that greatly outweighs any possible utility. The act of sale of the VCDs by Defendant constituted an affirmative act in conjunction with the accompanying labels and other documents, representing that the VCDs were safe, of the specified quality, and met all applicable standards, including but not limited to USP, Orange Book, and other applicable regulations.

333. Defendant engaged in deceptive conduct because the affirmative misrepresentations and omissions at issue were likely to, and in fact did, mislead, deceive, or cheat reasonable purchasers including Plaintiffs and other Class Members, who relied on these

misrepresentations and omissions. In addition, the misrepresentations and omissions were the type that tend to create a false impression. Reasonable consumers, including Plaintiffs and other Class Members, would have found it material to their purchasing or reimbursing decisions that the VCDs were not therapeutically equivalent to FDA-approved Chantix, were unapproved new drugs, contained undisclosed safety risks, were contaminated with nitrosamines, were not made in accordance with cGMPs, and were adulterated, misbranded, and illegal to sell. Knowledge of these facts would have been a substantial factor in Plaintiffs' and other Class Members' decisions to pay for VCDs, and they would not have made these payments in the absence of Defendant's wrongful conduct.

334. Defendant's advertising in the conduct of business was deceptive because the misrepresentations and omissions had the capacity, tendency, and effect of deceiving reasonable consumers, including the Plaintiffs. Reasonable consumers, including Plaintiffs and other Class Members, would have found it material to their purchasing decisions that the VCDs were not therapeutically equivalent to FDA-approved Chantix, were unapproved new drugs, contained undisclosed safety risks, were contaminated with nitrosamines, were not made in accordance with cGMPs, and were adulterated, misbranded, and illegal to sell. Knowledge of these facts would have been a substantial factor in Plaintiffs' and other Class Members' decisions to pay for VCDs, and they would not have made these payments in the absence of Defendant's wrongful conduct.

335. To the extent applicable, Defendant knew, intended, or should have known that its fraudulent and deceptive acts, omissions, or concealment would and did induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages— an ascertainable loss — in an amount to be proved at trial.

336. Plaintiffs and other Class Members justifiably relied on Defendant's representations that the VCDs they were purchasing were safe, therapeutically equivalent to FDA-approved Chantix, were not new unapproved drugs, did not contain any undisclosed risks, were not contaminated with nitrosamines, were made in accordance with cGMPs, and were not adulterated or misbranded. Plaintiffs and other Class Members further relied on the Defendant's advertised reputations and representations that they exercised the highest degree of care to ensure safety and quality at all times, along with their failure to disclose the contamination of VCDs and manufacturing and quality control problems, and the Defendant's affirmative assurances that its VCDs were safe for human consumption and/or ingestion.

337. Defendant engaged in unfair and deceptive conduct by misleading, through affirmative misrepresentation and omission, consumers and TPPs as to the content of the VCDs. In fact, the products never should have been offered to consumers in the first place, and could not have been in the absence of the stated wrongful conduct.

338. As demonstrated herein, Defendants engaged in patently unlawful conduct through their manufacturing, receipt, and sale of contaminated, adulterated and misbranded prescription drugs. *See, e.g.*, 21 U.S.C. §§ 331(a)-(c), (g) (as incorporated by states' laws).

339. Defendant's conduct actually and proximately caused actual damages to Plaintiffs and other Class Members. Absent Defendant's unfair and deceptive conduct, Plaintiffs and other Class Members would have behaved differently and would not have purchased the VCDs. Defendant's misrepresentations and omissions induced Plaintiffs to purchase the VCDs they would not otherwise have purchased, economically harming and damaging Plaintiffs.

340. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages—an ascertainable loss—in an amount to be proved at trial.

COUNT VII
NEGLIGENCE

341. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

342. Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing, distribution, and sale of its VCDs.

343. Defendant owed a duty to Plaintiffs and the Class to ensure that the VCDs it sold in the United States were therapeutically equivalent to branded Chantix and complied with cGMPs and were not adulterated or misbranded.

344. Defendant owed a duty of care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of VCDs and victims of Defendant's fraudulent and deceptive activities. Defendant knew, or should have known, that its VCDs were not therapeutically equivalent to branded Chantix and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

345. Defendant failed to do this. Defendant inadequately oversaw the manufacture and sale of its own VCDs. Defendant knew that ignoring the manufacturing issues surrounding its VCDs would damage Plaintiffs and the Class and increase its own profits.

346. Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its VCDs complied with cGMPs and was not adulterated or misbranded.

347. Defendant had a duty to exercise reasonable care in the manufacture, quality control, and distribution of VCDs. Defendant's failure to exercise this duty, in spite of knowing or recklessly disregarding the risks of nitrosamine contamination and related cGMP deviations or failures that meant Defendant could not assure that its VCDs were of appropriate quality, identity, purity, or strength, was a breach of Defendant's duty.

348. Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its VCDs.

349. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Plaintiffs and Class members to pay or reimburse for Defendant's VCDs.

350. Defendant knew or should have known prior to initiating recalls in the United States about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

351. Defendant knowingly, recklessly, or negligently represented that its VCDs were manufactured in a cGMP manner and that its VCDs were what they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory

guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

352. Defendant had direct or constructive knowledge of the risks of NDMA contamination at least as early as 2018 (and likely much sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, Defendant knew, and certainly should have known, of the possibility of nitrosamine formation in its VCDs, particularly because regulators including the FDA issued guidance in the second half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just like those used by Defendant to make its VCDs. Further, Health Canada specifically warned firms including Defendant about nitrosamine formation in VCDs in October 2020. Yet, Defendant sat by idly and did nothing in the United States until it began VCD recalls in the summer of 2021.

353. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that nitrosamine contamination occurred in VCDs potentially due to the similar route of contamination that resulted in nitrosamine contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started three years before Defendant's recalls of its VCDs.

354. Thus, prior to initiating recalls of VCDs in the United States, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, Health Canada's actions in 2020, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But Defendant intentionally, recklessly,

or negligently disregarded that knowledge in making its representations that were false or deceptive about its VCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a cGMP compliant manner, each of which was false and either of which rendered the VCDs adulterated and misbranded.

355. Defendant's specific statements and omissions go beyond simply naming their VCDs "Chantix." Defendant's marketing and labeling carried with it the assurance, as required by state laws incorporating federal law, that the product did not contain any undisclosed contaminants, that VCDs had the same efficacy *and* safety profile as FDA-approved Chantix, and that the VCDs were not made in a non-cGMP compliant manner. Defendant omitted the material information that VCDs were not what they purported to be, insofar as they contained undisclosed dangerous nitrosamine contaminants, were not as safe as FDA-approved Chantix, and were not made in a cGMP-compliant manner. As such, the VCDs were adulterated and misbranded, which are illegal to sell. No Plaintiff or Class Member could ever buy an adulterated drug; thus, Defendant's distribution and sale of its VCDs in the first instance was a representation that the drugs were not adulterated.

356. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other. This relationship arose because Defendant, as a pharmaceutical drug manufacturer, owes a distinct duty to consumers of its highly regulated pharmaceutical products, to be ingested by Plaintiffs and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its VCDs further bolstered the special relationship and distinct duty.

357. In addition, state drug regulation laws impose an independent duty on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in

accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health-General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;

- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

358. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

359. Defendant breached duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

360. As a direct and proximate result of Defendant's negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

COUNT VIII
NEGLIGENCE PER SE

361. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

362. Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacture, distribution, and sale of its VCDs.

363. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

364. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to pay or reimbursement for Defendant's VCDs.

365. Defendant knew or should have known prior to initiating recalls in the United States about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

366. Defendant knowingly, recklessly, or negligently represented that its VCDs were manufactured in a cGMP manner and that its VCDs were what they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

367. Defendant had direct or constructive knowledge of the risks of NDMA contamination at least as early as 2018 (and likely much sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, Defendant knew, and certainly should have known, of the possibility of nitrosamine formation in its VCDs, particularly because regulators including the FDA issued guidance in the second half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just like those used by Defendant to make its VCDs. Further, Health Canada specifically warned firms including Defendant about nitrosamine formation in VCDs in October 2020. Yet, Defendant sat by idly and did nothing in the United States until it began VCD recalls in the summer of 2021.

368. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that nitrosamine contamination occurred in VCDs potentially due to the similar route of contamination that resulted in nitrosamine contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started three years before Defendant's recalls of its VCDs.

369. Thus, prior to initiating recalls of VCDs in the United States, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, Health Canada's actions in 2020, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about its VCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a cGMP compliant manner, each of which was false and either of which rendered the VCDs adulterated and misbranded.

370. Defendant's specific statements and omissions go beyond simply naming their VCDs "Chantix." Defendant's marketing and labeling carried with it the assurance, as required by state laws incorporating federal law, that the product did not contain any undisclosed contaminants, that VCDs had the same efficacy *and* safety profile as FDA-approved Chantix, and that the VCDs were not made in a non-cGMP compliant manner. Defendant omitted the material information that VCDs were not what they purported to be, insofar as they contained undisclosed dangerous nitrosamine contaminants, were not as safe as FDA-approved Chantix, and were not made in a cGMP-compliant manner. As such, the VCDs were adulterated and misbranded, which are illegal to sell. No Plaintiff or Class Member could ever buy an adulterated drug; thus, Defendant's distribution and sale of its VCDs in the first instance was a representation that the drugs were not adulterated.

371. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other.

372. This relationship arose because Defendant, as a pharmaceutical drug manufacturer owes a distinct duty to consumers of its highly regulated pharmaceutical products, to be ingested by Plaintiffs and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its VCDs further bolstered the special relationship and distinct duty.

373. In addition, state drug regulation laws impose an independent duty on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- a. Alabama Code §§ 20-1-24 and -27(1);

- b. Alaska Statutes § 17.20.290(a)(1);
- c. Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- d. Arkansas Code § 20-56-215(1);
- e. California Health and Safety Code §§ 111295 and 111400;
- f. Colorado Statutes §§ 25-5-403(1)(a), (b) and -414(1)(c);
- g. Title 16, Delaware Code §§ 3302 and 3303(2);
- h. District of Columbia Code § 48-702(2);
- i. Florida Statutes §§ 499.005(1) and .006(3);
- j. Georgia Code § 26-3-3(1);
- k. Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- l. Idaho Code § 37-115(a);
- m. Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- n. Iowa Code §§ 126.3(1) and .9(1)(c);
- o. Kentucky Statutes § 217.175(1);
- p. Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- q. Massachusetts General Laws chapter 94 §§ 186 and 190;
- r. Minnesota Statutes §§ 151.34(1) and .35(1);
- s. Missouri Statutes § 196.015(1);
- t. Montana Code §§ 50-31-305(3) and -501(1);
- u. Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- v. Nevada Statutes § 585.520(1);
- w. New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- x. New Mexico Statutes §§ 26-1-3(A) and -10(A);

- y. New York Education Law § 6811;
- z. North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- aa. Ohio Code § 3715.52(A)(1);
- bb. Oklahoma Statutes title 63 § 1-1402(a);
- cc. Title 35, Pennsylvania Statutes § 780-113(a)(1);
- dd. Title 21, Rhode Island General Laws § 21-3-3(1);
- ee. South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- ff. South Dakota Code §§ 39-15-3 and -10;
- gg. Title 18, Vermont Statutes § 4052(1);
- hh. Virginia Code § 54.1-3457(1);
- ii. West Virginia Code §§ 16-7-1 and -2(a)(3); and
- jj. Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

374. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

375. As a result of Defendant's failures to do so, Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

376. As a direct and proximate result of Defendant's negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

COUNT IX
UNJUST ENRICHMENT

377. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

378. As alleged herein, Defendant was unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendant's VCDs.

379. Defendant profited immensely from introducing a carcinogen into the United States for human consumption, and an unapproved drug that was not made in a cGMP-compliant manner. On top of that, because Defendant's VCDs were adulterated and misbranded, their distribution and sale in the United States was illegal. Defendants' VCDs were not safe as warranted, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

380. Plaintiff and other Class Members were unjustly deprived of money obtained by Defendant as a result of the improper amounts paid for Defendant's VCDs. It would be inequitable and unconscionable for Defendant to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of its wrongful conduct alleged in this Complaint. There is no adequate remedy at law for Plaintiffs and other Class Members, especially in the alternative that the lack of a quasi-contractual relationship or common-law duty is found not to exist between Defendant and Plaintiff and other Class Members.

381. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendant by virtue of its wrongful conduct.

PRAYER FOR RELIEF

For these reasons, Plaintiffs prays for the following judgment:

- a. An order certifying this action as a class action;
- b. An order appointing Plaintiffs as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

- c. A declaration that Defendant is liable under each and every one of the above-enumerated causes of action;
- d. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendant described above;
- e. Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the VCDs; the costs to replace or return VCDs because of recalls; and the increases in the amounts paid for non-adulterated, non-misbranded, VCDs in the wake of the recalls;
- f. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;
- g. An award of statutory penalties to the extent available;
- h. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and
- i. Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: May 5, 2023

Respectfully submitted,

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